[DISCUSSION DRAFT]

114TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

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

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 ''_____ Act of 2015''.

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

SEC. 2. IN VITRO CLINICAL TESTS DEFINED.

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

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

''(A) means a laboratory test protocol or finished product intended by its developer to be used in the collection, preparation, analysis, or in vitro clinical examination of specimens taken or derived from the human body, solely or principally for the purpose of identifying, measuring, predicting, monitoring, or assisting in selecting treatment for, a disease or other condition;

''(B) excludes any test that—

''(i) meets the definition of a 'biological product' under section 351 of the Public Health Service Act; and

''(ii) is intended to—

''(I) screen human blood, human cells, tissues, cellular or tissue-based products (HCT/Ps), or organs for infectious diseases; or

''(II) determine the compatibility of a donor or patient to ensure the safe transfusion or transplantation of blood, human cells, tissues, cellular or tissue-based products (HCT/Ps), or organs; and

''(C) excludes any test intended by its developer solely for nonclinical use, such as a test intended by its developer solely for purposes of forensic testing, drugs-of-abuse testing for employment, insurance, and genetic testing for nonclinical purposes.

''(2) The term 'laboratory test protocol'—

''(A) means the final design of a test not produced, provided, purchased, or sold as a finished product; and

''(B) excludes standard operating procedures for performance of an in vitro clinical test.

''(3) The term 'finished product'—

''(A) means an article of personal property other than a laboratory test protocol that is suitable

for use and capable of functioning for its intended purpose without further production activity; and

''(B) excludes any component, part, or raw material.''.

(b) EXCLUSION FROM DEFINITIONS OF DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS.—

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

(2) DEVICE DEFINITION.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by inserting ''excludes any in vitro clinical test and any component, part, raw material, or accessory of an in vitro clinical test and'' before ''(except when''.

(3) BIOLOGICAL PRODUCT.—Section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)) is amended by striking ''means'' and inserting ''excludes any in vitro clinical test and any component, part, raw material, or accessory of an in vitro clinical test and means''.

SEC. 3. REGULATION OF IN VITRO CLINICAL TESTS.

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

"Subchapter J—In Vitro Clinical Tests

"SEC. 590. REGULATION OF IN VITRO CLINICAL TEST DEVELOPMENT ACTIVITIES.

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

''(b) SCOPE OF AUTHORITY.—

''(1) IN GENERAL.—The design, development, validation, production, manufacture, preparation, propagation, assembly, and processing of an in vitro clinical test—

''(A) shall be regulated by the Secretary under this subchapter; and

''(B) shall not be regulated by the Secretary under section 353 of the Public Health Service Act.

''(2) LIMITATIONS.—

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

"(B) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

"(i) IN GENERAL.—The provisions of this subchapter shall not apply to a test intended to be used solely for public health surveillance.

"(ii) DEFINITION.—In this subparagraph, the term 'public health surveillance' means ongoing systematic activities, including collection, analysis, and interpretation of health-related data, essential to planning, implementing, and evaluating public health practice.

"(C) OTHER LIMITATIONS.—

"(i) NO INTERFERENCE WITH HEALTH CARE PRACTICE.—Nothing in this subchapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe, order, or use the results of an in vitro clinical test for any condition or disease within a legitimate health care practitioner-patient relationship.

"(ii) OTHER ACTIVITIES.—The Secretary shall not regulate the following ac-

tivities under this subchapter when undertaken by a pathologist, laboratory physician, other physician, laboratory scientist, or other health care practitioner:

"(I) Recommending appropriate patient-specific in vitro clinical tests.

"(II) Rendering a diagnosis as a result of a specimen review.

"(III) Interpreting data generated by an in vitro clinical test.

"(IV) Dialog with a health care practitioner regarding scientific information about an in vitro clinical test.

"(V) Assessing in vitro clinical test output related to a specific patient.

"(c) AGENCY CENTER.—Not later than 90 calendar days after the date of enactment of the _____ Act of 2015, the Secretary shall establish within the Food and Drug Administration the Center for In Vitro Clinical Tests, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this subchapter and closely related matters assigned by the Com-

missioner. Senior management of the Center shall include at least one person with management experience in clinical laboratory operations.

''(d) DEFINITIONS.—In this subchapter:

''(1) The terms 'analytical validity' and 'analytically valid' mean, with respect to an in vitro clinical test, the ability of the test to identify, measure, calculate, or analyze one or more analytes, biomarkers, substances, or other targets sought to be identified, measured, calculated, or analyzed by the test, as measured by, for example, sensitivity, specificity, accuracy, precision, reference range, and reportable range.

''(2) The terms 'clinical validity' and 'clinically valid'—

''(A) mean, with respect to an in vitro clinical test, the reliability and accuracy with which the test—

''(i) identifies, measures, predicts, monitors, or assists in selecting treatment for, a disease or condition in humans; or

''(ii) identifies, measures, predicts, or monitors characteristics related to an individual's clinical status; and

''(B) excludes clinical utility.

''(3) The term 'developer' means the person responsible for the design, development, validation, production, manufacture, preparation, propagation, assembly, processing, or initial importation of an in vitro clinical test.

''(4)(A) The term 'intended use' means the developer's stated purpose for the in vitro clinical test.

''(B) The intended use of an in vitro clinical test shall not be determined using any of the following:

''(i) Scientific or medical communication or collaboration between the developer of the in vitro clinical test and the operator of a laboratory or another health care practitioner that uses or may use the test.

''(ii) Communication between the developer of an in vitro clinical test and a prospective purchaser or user regarding the developer's in vitro clinical test then in development.

''(iii)(I) Health care economic information provided to an entity for the purpose of carrying out such entity's responsibilities for the selection of in vitro clinical tests for coverage, reimbursement, or inclusion in a formulary.

''(II) In this clause, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences of the use of an in vitro clinical test to—

''(aa) another in vitro clinical test;

''(bb) another test or intervention; or

''(cc) no test or intervention.

''(5) The terms 'laboratory', 'laboratory operations', and 'standard operating procedures' have the meanings given to such terms in section 353(a)(2) of the Public Health Service Act.

''(6) The term 'mitigating measures' means, with respect to an in vitro clinical test, one or more measures that the Secretary determines, based on available evidence, are necessary to provide a reasonable assurance of the analytical validity and clinical validity, or probable clinical validity, as applicable, of an in vitro clinical test for its intended use, in a particular risk classification.

''(7) The term 'offer' means to make available for purchase, order, prescription, or use.

''(8) The term 'platform' means an in vitro clinical test that is hardware intended by the hardware's developer to be used with one or more in vitro clin-

ical tests to generate a clinical test result, including software used to effectuate the hardware's functionality.

''(9) The term 'reasonable assurance' means the degree of valid scientific evidence for in vitro clinical tests needed to demonstrate analytical validity or clinical validity, for the intended use of the in vitro clinical test, as applicable, which may vary based upon the relevant—

''(A) population size;

''(B) disease state;

''(C) demographic representation;

''(D) limit of detection or analytical sensitivity;

''(E) disease or condition;

''(F) type of use claim (such as predictive, prognostic, diagnostic, monitoring, treatment selection, and screening uses);

''(G) risk classification;

''(H) availability of warnings and restrictions or other mitigating measures;

''(I) use environment;

''(J) user;

''(K) feasibility of data collection;

''(L) impact of requiring additional data collection on innovation;

''(M) experience with similar in vitro clinical tests;

''(N) ease of use; or

''(O) other factors.

''(10)(A) The term 'valid scientific evidence' means, with respect to an in vitro clinical test, evidence—

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

''(ii) for which it can be fairly and responsibly concluded by qualified experts that there is a reasonable assurance of analytical validity and clinical validity, or probable clinical validity where applicable, of the in vitro clinical test for its intended use.

''(B) Subject to subparagraph (A), the term 'valid scientific evidence' may, with respect to an in vitro clinical test, include, alone or in combination—

''(i) peer reviewed literature;

''(ii) clinical guidelines;

''(iii) reports of significant human experience with an offered 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; and

''(xi) clinical trials.

''SEC. 590A. CLASSIFICATION OF IN VITRO CLINICAL TESTS.

''(a) RISK CLASSIFICATION.—

''(1) IN GENERAL.—The Secretary shall, based on the intended use of an in vitro clinical test, establish the following risk classes:

''(A) High-risk.

''(B) Moderate-risk.

''(C) Low-risk.

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

''(A) a clinically significant inaccurate result for the intended use would cause serious or irreversible harm, or death, to the patient or public based on failure to treat, incorrect treat-

ment, invasive procedures, or prolonged disability if such inaccurate result were undetected when used as intended in medical practice;

"(B) none of the factors specified in paragraph (5) are available to prevent or detect such inaccurate result or otherwise mitigate the risk of such inaccurate result; and

"(C) the risk of adverse patient impact or adverse public health impact caused by an inaccurate result is not remote.

"(3) MODERATE-RISK CLASS.—An in vitro clinical test shall be regulated as moderate-risk if—

"(A) the test meets the criteria specified in paragraph (2)(A) for classification as high-risk, but one or more mitigating factors described in paragraph (5) is available to prevent or detect the clinically significant inaccurate result or otherwise mitigate the risk; or

"(B)(i) a clinically significant inaccurate result for the intended use would cause non-life-threatening injury, injury that is medically reversible, or delay in necessary treatment if such inaccurate result were undetected when used as intended in medical practice;

''(ii) none of the mitigating factors described in paragraph (5) are available to prevent or detect such inaccurate result or otherwise mitigate the risk of such inaccurate result; and

''(iii) the risk of adverse patient impact or adverse public health impact caused by an inaccurate result is not remote.

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

''(A) the test meets the criteria for classification as moderate-risk specified in subparagraph (3)(B)(i), but one or more mitigating factors described in paragraph (5) is available to prevent or detect the clinically significant inaccurate result or otherwise mitigate the risk;

''(B) a clinically significant inaccurate result for the intended use would cause minimal or no harm, immediately reversible harm, or no disability if such inaccurate result were undetected when used as intended in medical practice; or

''(C) the risk of adverse patient impact or adverse public health impact caused by an inaccurate result is remote.

''(5) MITIGATING FACTORS.—A mitigating factor described in this paragraph is one of the following:

''(A) The test's technology and clinical use are well characterized.

''(B) Clinical presentation.

''(C) The availability of—

''(i) other tests, such as confirmatory or adjunctive tests; or

''(ii) relevant materials standards.

''(D) Such other factors as the Secretary considers necessary.

''(E) Mitigating measures.

''(b) PRECLASSIFICATION MEETING.—Before submitting a request under subsection (c) or (d) for classification or reclassification, as applicable, of an in vitro clinical test—

''(1) the developer of the test may submit to the Secretary a written request for a meeting to discuss and provide information relating to classification or reclassification of the test; and

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

''(A) within 30 calendar days after such receipt, meet with the developer submitting the request; and

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

''(c) CLASSIFICATION PROCESS.—

''(1) CLASSIFICATION BY OPERATION OF LAW.—If a type of in vitro clinical test has been classified by the Secretary under this section, and such classification remains in effect, any in vitro clinical test within such type is deemed to be in the same class.

''(2) CLASSIFICATION BY SECRETARY.—

''(A) SUBMISSION OF REQUEST.—In the case of an in vitro clinical test that is not classified pursuant to paragraph (1) or subsection (e), the developer of the in vitro clinical test may submit a request to the Secretary for classification of the in vitro clinical test.

''(B) FORM OF REQUEST.—A request under subparagraph (A) shall be in such form, submitted in such manner, and contain such information as the Secretary may require. At a

minimum, any such request shall contain each of the following:

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

"(ii) A recommended classification, including a rationale for the recommended classification.

"(iii) Proposed mitigating measures, if any, and an explanation of how the proposed mitigating measures support the recommended classification.

"(C) DISPOSITION OF REQUEST.—The Secretary shall—

"(i) not later than 60 calendar days after receiving a request under subparagraph (B), issue an administrative order—

"(I) rejecting, modifying, or accepting the recommended classification of the in vitro clinical test; and

"(II) explaining the reasons for such decision and in the case of a modification or rejection, the reason

for the modification or rejection, including the reasons why the information and explanations submitted by the developer (including any valid scientific evidence for the in vitro clinical test involved) do not support the recommended classification; and

''(ii) not later than 60 calendar days after issuing an order under clause (i) with respect to a recommended classification for an in vitro clinical test—

''(I) publish a notice in the Federal Register announcing the classification; and

''(II) revise, as appropriate, regulations to include such classification.

''(iii) revoke or revise, as appropriate, any regulation or requirement issued in connection with the in vitro clinical test's previous classification

''(D) CLASSIFICATION APPEALS.—In the case of a modification or rejection of a recommended classification of an in vitro clinical test by order issued by the Secretary under subparagraph (C)(i) or the Secretary's failure to

issue an order within the timeframes specified in such subparagraph—

"(i) such modification or rejection or failure shall be treated as final and immediately subject to appeal under section 590G; and

"(ii) not later than 180 calendar days after the date on which such modification or rejection is issued, the developer of the test may, as part of such an appeal, request review of the recommended classification by an advisory panel.

"(3) MULTIPLE INTENDED USES.—If a type of in vitro clinical test has multiple intended uses, any such test shall be classified based on the intended use of the highest risk class.

"(4) ACCESSORIES; PLATFORMS.—

"(A) ACCESSORIES.—

"(i) IN GENERAL.—An in vitro clinical test, that is intended by its developer to be used as an accessory to another in vitro clinical test, shall be classified according to its intended use and independently of any classification of any in vitro clinical test with which it is used.

''(ii) DEFINITION.—In this subparagraph, the term 'accessory' means a standalone item intended by its developer to be used in conjunction with one or more particular in vitro clinical tests to enable or assist the in vitro clinical test in performing its intended use.

''(B) PLATFORMS.—A platform shall be classified and regulated under this title separately from the in vitro clinical test with which it is used and shall be classified as low-risk. An in vitro clinical test intended to be performed on the platform shall be classified according to its intended use and independently of the platform.

''(d) RECLASSIFICATION PROCESS.—

''(1) IN GENERAL.—Based on new information respecting an in vitro clinical test when used in accordance with its intended use, the Secretary may, upon the Secretary's own initiative or upon petition of an interested person, by administrative order published in the Federal Register—

''(A) change such in vitro clinical test's classification; and

"(B) revoke or revise, as appropriate, any regulation or requirement issued in connection with the in vitro clinical test's previous classification.

"(2) RECOMMENDATIONS OF ADVISORY PANEL.—In publishing an order under paragraph (1)—

"(A) the Secretary may secure, or the interested person may require that the Secretary secure, from an advisory panel, a recommendation respecting the proposed change in the in vitro clinical test's classification; and

"(B) the Secretary shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change.

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

"(4) DOWN-CLASSIFICATION.—

"(A) IN GENERAL.—If the Secretary, upon the Secretary's own initiative or upon petition, intends to make a down-classification of an in

vitro clinical test, the Secretary shall publish a notice in the Federal Register of such intent. Such notice shall—

"(i) in the case of the Secretary intending to modify or add mitigating measures applicable to the test involved—

"(I) describe and provide justification for such mitigating measures; and

"(II) provide for a 90-calendar-day public comment period; and

"(ii) in the case of the Secretary not intending to modify or add any such mitigating measures, provide for a 60-calendar-day public comment period.

"(B) PREVENTION OF UP-CLASSIFICATION.—In the case of an in vitro clinical test that the Secretary determines would be up-classified but for the withdrawal, modification, or addition of mitigating measures applicable to an in vitro clinical test, the Secretary shall publish in the Federal Register a notice of the Secretary's intent to withdraw, modify, or add such mitigating measures. Such notice shall—

"(i) describe and provide justification for such mitigating measures; and

"(ii) provide for a 90-calendar-day public comment period.

"(C) FINAL DETERMINATION.—Not later than 60 calendar days after the close of the applicable public comment period under subparagraph (A) or (B), the Secretary shall—

"(i) decide whether to make the down-classification of the in vitro clinical test involved;

"(ii) publish a notice of such decision in the Federal Register;

"(iii) if the Secretary decides to make the down-classification, publish an administrative order—

"(I) in accordance with paragraph (1); and

"(II) describing and providing justifications for any mitigating measures applicable to such down-classification; and

"(iv) revoke or revise, as appropriate, any regulation or requirement issued in

connection with the in vitro clinical test's previous classification.

''(D) TRANSITION TO MITIGATING MEASURES.—When the Secretary establishes a mitigating measure, including any mitigating measure established pursuant to subsection (d)(4), specifying a new or different performance standard, the Secretary shall provide an appropriate transition period with respect to—

''(i) in vitro clinical tests under premarket review; and

''(ii) in vitro clinical tests not under premarket review, but for which the mitigating measures are inconsistent with documented advice provided to the developer by the Food and Drug Administration.

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

''(A) shall make the up-classification by administrative order;

''(B) shall revoke or revise, as appropriate, any regulation or requirement issued in connection with the in vitro clinical test's previous classification; and

"(C) shall not delegate authority to make the up-classification to any employee or official other than the chief scientific officer of the Center for In Vitro Clinical Tests or another member of the senior management of such Center.

"(6) RECLASSIFICATION APPEALS.—In the case of a modification or rejection of a recommended classification change of an in vitro clinical test under paragraph (1) or failure to make a determination with respect to a down-classification within the timeframe specified in paragraph (4)(C)—

"(A) such modification, rejection, or failure shall be treated as final and immediately subject to appeal under section 590G; and

"(B) not later than 180 calendar days after the date of such modification, rejection, or failure, the developer of the test may, as part of such an appeal, request review of the recommended classification by an advisory panel.

"(e) INITIAL CLASSIFICATION OF PREVIOUSLY CLASSIFIED IN VITRO CLINICAL TESTS.—

"(1) IN GENERAL.—An in vitro clinical test classified under section 513(a) as of the date of en-

actment of the _____ Act of 2015 shall be classified as follows:

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

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

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

"(2) CONTINUED APPLICATION OF MITIGATING MEASURES.—An in vitro clinical test described in paragraph (1) that is subject to one or more mitigating measures as of the date specified in such paragraph shall continue to be subject to such mitigating measures after such date, unless—

"(A) the classification of the test is changed under this subsection; or

"(B) the mitigating measures applicable to such classification are changed pursuant to this subsection.

"(3) PUBLIC COMMENT.—Not later than 60 calendar days after the date of enactment of the _____ Act of 2015, the Secretary shall—

"(A) publish a notice in the Federal Register that—

"(i) identifies, with supporting scientific rationale, all in vitro clinical tests for which the Secretary believes the classification pursuant to paragraph (1) is incorrect;

"(ii) requests that interested persons—

"(I) notify the Secretary of any in vitro clinical test for which the interested person believes the classification pursuant to paragraph (1) is incorrect; and

"(II) provide supporting scientific rationale for such belief; and

"(iii) requests that interested persons—

"(I) notify the Secretary of any in vitro clinical test offered as of the date of the enactment of the _____ Act of 2015, which was not classified

under section 513(a) as of such date; and

"(II) provide a suggested classification with supporting scientific rationale; and

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

"(4) REVIEW AND RECOMMENDATIONS BY ADVISORY PANELS.—

"(A) IN GENERAL.—Not later than 90 calendar days after the date of enactment of the _____ Act of 2015, the Secretary shall identify or establish one or more advisory panels (in this subsection referred to as an 'advisory panel')—

"(i) to review and consider the classification of each in vitro clinical test identified by the Secretary or an interested person pursuant to paragraph (3); and

"(ii) to recommend the appropriate classification of each such test in accordance with this section.

"(B) MEMBERSHIP.—The members of an advisory panel shall include a balanced representation of interested persons representing

physicians, consumers, and the in vitro clinical test manufacturing and laboratory industries.

''(C) INAPPLICABLE REQUIREMENTS.—Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

''(5) TIMING OF RECOMMENDATIONS.—

''(A) ASSIGNMENT TO ADVISORY PANEL.—Not later than 180 calendar days after the close of the public comment period under paragraph (3)(B) with respect to an in vitro clinical test, the Secretary shall direct the respective advisory panel to conduct the review required by paragraph (4).

''(B) ISSUANCE OF RECOMMENDATION.—Not later than 1 year after the Secretary directs an advisory panel to review the classification of an in vitro clinical test under subparagraph (A), the advisory panel shall, after taking into consideration all public comments and, at the advisory panel's discretion, holding public meetings, provide to the Secretary the advisory panel's recommended classification of the in vitro clinical test.

''(6) CLASSIFICATION DETERMINATION.—

''(A) CLASSIFICATION.—Not later than 180 calendar days after the date on which the Secretary receives the recommendation of an advisory panel with respect to the classification of an in vitro clinical test under paragraph (5), the Secretary shall by administrative order published in the Federal Register—

''(i) classify the in vitro clinical test in accordance with the classes specified in this section and publish such classification in the Federal Register;

''(ii) if such classification differs from the classification recommended by the advisory panel, specifically rebut the advisory's panel's classification with scientific evidence;

''(iii) in the case of an up-classification, include a public health justification demonstrating the need for up-classification; and

''(iv) subject to a final classification determination under subparagraph (C)(iii), revoke or revise, as appropriate, any regulation or requirement issued in connection

with the in vitro clinical test's previous classification.

"(B) FINALITY OF CLASSIFICATION.—Subject to subparagraph (C), a classification under subparagraph (A)(i) is deemed to be final upon publication.

"(C) EXCEPTION FOR UP-CLASSIFICATION.—With respect to any up-classification published under subparagraph (A), the Secretary—

"(i) shall provide a 60-calendar-day period for public comment;

"(ii) shall not delegate authority to make the up-classification to any employee or official other than the chief scientific officer of the Center for In Vitro Clinical Tests or another member of the senior management of such Center; and

"(iii) not later than 90 calendar days after the close of the public comment period under clause (i), shall publish in the Federal Register the final classification for such in vitro clinical test.

"(7) INACTION BY THE SECRETARY.—If the Secretary fails to issue a final classification deter-

mination for an in vitro clinical test or type of in vitro clinical test within the timeframes described in paragraph (6), it shall be presumed that the classification recommended by the advisory panel is the final classification of the in vitro clinical test or type of in vitro clinical test. Not later than 90 calendar days after the timeframes described in paragraph (6), the Secretary shall publish in the Federal Register final classification determinations for all such in vitro clinical tests and types of in vitro clinical tests taking into account the presumed classification. If the Secretary determines that the final classification differs from the presumed classification, the Secretary shall rebut such presumption using scientific evidence in the Federal Register.

''(8) DEEMED CLASSIFICATION TO BECOME FINAL.—The deemed classification under paragraph (1) shall be the final classification of any in vitro clinical test not submitted to an advisory panel pursuant to paragraph (5).

''(9) APPEAL OF CLASSIFICATION.—Not later than 60 calendar days after the date of the final classification of an in vitro clinical test under paragraph (6) or (7), the developer of the test may appeal such classification under section 590F.

''(f) DEFINITIONS.—In this section:

''(1) DOWN-CLASSIFICATION.—The term 'down-classification' means—

''(A) reclassification from high-risk to moderate- or low-risk; or

''(B) reclassification from moderate-risk to low-risk.

''(2) UP-CLASSIFICATION.—The term 'up-classification' means—

''(A) reclassification from low-risk to moderate- or high-risk; or

''(B) reclassification from moderate-risk to high-risk.

''(3) WELL-CHARACTERIZED.—The term 'well-characterized' means well-established and well-recognized by the medical community, as evidenced by one or more of the following:

''(A) 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) Wide recognition or adoption by the medical community.

''(H) Proficiency testing.

"SEC. 590B. PREMARKET REVIEW.

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

''(b) PRESUBMISSION MEETING.—Before submitting an application or notification under subsection (c) or (d) for offering 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 submission process and the type and amount of evidence expected to demonstrate a reasonable assurance of analytical validity and clinical validity, or probable clinical validity, as applicable; and

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

''(A) within 30 calendar days after such receipt, meet or confer with the developer submitting the request; and

''(B) within 30 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.

''(c) PREMARKET APPROVAL OF HIGH-RISK TESTS.—

''(1) IN GENERAL.—The Secretary shall approve a high-risk in vitro clinical test (other than an in vitro clinical test submitted for approval under subsection (f)) if, upon the submission to the Secretary of an application by the developer of the test, the Secretary determines that the application demonstrates a reasonable assurance that the in vitro clinical test is analytically valid and clinically valid for its intended use.

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

''(A) the name, address, and establishment registration number of the developer of the test;

''(B) in the case of an application submitted by a person other than the developer, the name, address, and establishment registration number, if applicable, of the applicant;

''(C) the name of the in vitro clinical test;

''(D) the intended use of the in vitro clinical test;

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

''(i) the analyte, biomarker, substance, or other target sought to be identified, measured, calculated, or analyzed by the test;

''(ii) the specifications of the test;

''(iii) specimen types to be analyzed by the test;

''(iv) the indications for use of the test;

''(v) the intended users of, and user environments for, the test;

''(vi) brief descriptions of components of the test;

''(vii) principles of properties of the test or the principles of operation of the test;

''(viii) the software necessary for application of the test, including risk mitigation for cybersecurity;

''(ix) any quality controls applicable to the use of the test; and

''(x) the method of specimen collection and transport to be used with the test;

"(F) applicable performance standards, voluntary standards, or mitigating measures relied upon by the developer in determining the analytical and clinical validity of the test;

"(G) a summary of design controls for the test and a declaration of the developer's conformity to such design controls;

"(H) in the case of an in vitro clinical test that is a finished product, a summary of relevant process controls used in manufacturing the test, a validation master plan for such process, any acceptance activities or statistical techniques used to ensure the validity of results generated by the test, and any purchasing controls applicable to the test;

"(I) proposed labeling for the test that accounts for the differences between an in vitro clinical test that is a laboratory test protocol and an in vitro clinical test that is a finished product, as appropriate;

"(J) a risk assessment for the test;

"(K) a statement attesting to the truthfulness and accuracy of the submission;

"(L)(i) a summary of the valid scientific evidence that demonstrates a reasonable assur-

ance of analytical validity and clinical validity for the intended use of the in vitro clinical test; and

"(ii) the protocol and summary of results and conclusions from any studies performed with respect to such test, including, if the Secretary determines that such summary of results and conclusions is insufficient to demonstrate a reasonable assurance of analytical validity and clinical validity, and the Secretary notifies the developer in writing setting forth with specificity the basis for such insufficiency, the raw data from such studies.

"(3) APPROVAL PROCESS.—Not later than 120 calendar days after the date on which an application is submitted under paragraph (1), the Secretary shall—

"(A) issue an order approving or disapproving the application; and

"(B) in the case of an order disapproving the application, specify in such order the scientific rationale for such disapproval.

"(d) PREMARKET APPROVAL OF MODERATE-RISK TESTS.—

''(1) IN GENERAL.—The Secretary shall approve a moderate-risk in vitro clinical test (other than an in vitro clinical test submitted for approval under subsection (f)) if, upon the submission to the Secretary of an application by the developer of the test, the Secretary determines that the application demonstrates a reasonable assurance that the in vitro clinical test is analytically valid and clinically valid for its intended use.

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

''(A) the name, address, and establishment registration number of the developer of the test;

''(B) in the case of an application submitted by a person other than the developer, the name, address, and establishment registration number, if applicable, of the applicant;

''(C) the name of the in vitro clinical test;

''(D) the intended use of the in vitro clinical test;

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

''(i) the analyte, biomarker, substance, or other target sought to be identified,

measured, calculated, or analyzed by the test;

"(ii) the specifications of the test;

"(iii) specimen types to be analyzed by the test;

"(iv) the indications for use of the test;

"(v) the intended users of, and user environments for, the test;

"(vi) brief descriptions of components of the test;

"(vii) principles of properties of the test or the principles of operation of the test;

"(viii) the software necessary for application of the test, including risk mitigation for cybersecurity;

"(ix) any quality controls applicable to the use of the test; and

"(x) the method of specimen collection and transport to be used with the test;

"(F) applicable performance standards, voluntary standards, or mitigating measures relied upon by the developer in determining the analytical and clinical validity of the test;

"(G) a declaration of the developer's conformity to design controls;

"(H) proposed labeling for the test that accounts for the differences between an in vitro clinical test that is a laboratory test protocol and an in vitro clinical test that is a finished product, as appropriate;

"(I) a summary of the risk assessment for the test;

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

"(K)(i) a summary of the valid scientific evidence that demonstrates a reasonable assurance of analytical validity and clinical validity for the intended use of the in vitro clinical test; and

"(ii) a summary of the protocol and summary of results and conclusions from any studies performed with respect to such test.

"(3) APPROVAL PROCESS.—

"(A) IN GENERAL.—Not later than 75 calendar days after the date on which an application is submitted under paragraph (1), the Secretary shall—

"(i) issue an order approving or disapproving the application; and

"(ii) in the case of an order disapproving the application, specify in such order the scientific rationale for such disapproval.

"(B) DEEMED APPROVAL.—If the Secretary fails to issue an order under subparagraph (A) within the 75-calendar-day period specified in such subparagraph with respect to an in vitro clinical test, the in vitro clinical test is deemed to be approved.

"(4) THIRD-PARTY REVIEW AND APPROVAL PROCESS.—For purposes of reviewing and approving applications submitted under paragraph (1), the Secretary shall establish by regulation a process under which third parties may conduct such review and approval.

"(e) LISTING OF LOW-RISK TESTS.—A low-risk in vitro clinical test is deemed to be approved so long as the developer of the test submits a notification regarding the test to the Secretary in accordance with subsection (n).

"(f) SPECIAL PATHWAY FOR CERTAIN TESTS.—

''(1) STANDARD.—In lieu of approving a high- or moderate-risk in vitro clinical test under subsection (c) or (d), the Secretary shall—

''(A) approve such an in vitro clinical test under this subsection without confirmatory postmarket obligations if the developer of the test submits an application demonstrating a reasonable assurance of analytical validity and clinical validity for its intended use;

''(B) approve such an in vitro clinical test under this subsection subject to confirmatory postmarket obligations under paragraph (5) if the developer of the test submits an application demonstrating—

''(i) a reasonable assurance of analytical validity for its intended use and

''(ii) probable clinical validity for its intended use; and

''(C) continue an approval under subparagraph (B) in effect without confirmatory postmarket obligations under such subparagraph if the developer of the test submits a supplemental application under paragraph (7) with respect to the test and the Secretary—

''(i) finds that such application demonstrates a reasonable assurance of clinical validity for the intended use of the test; or

''(ii) does not disapprove the supplemental application under paragraph (8) by the deadline applicable under such paragraph.

''(2) ELIGIBILITY.—

''(A) IN GENERAL.—The in vitro clinical tests eligible for approval under this subsection consist of the following:

''(i) Unmet need in vitro clinical tests.

''(ii) Rare disease in vitro clinical tests.

''(iii) Moderate-risk in vitro clinical tests that offer a clinically significant advantage over in vitro clinical tests previously approved by the Secretary.

''(B) EXCEPTIONS.—An in vitro clinical test described in subparagraph (A) shall not be eligible for approval or continuation of approval under this subsection if—

''(i) a supplemental application submitted by the developer or its affiliate for

the in vitro clinical test was denied under paragraph (8); or

"(ii) an approval with confirmatory postmarket obligations under this subsection was granted to the developer or its affiliate for the in vitro clinical test and was withdrawn under paragraph (11).

"(C) ALTERNATIVE PATHWAYS.—If an in vitro clinical test meets the definition or criteria for more than one of the categories of rare disease in vitro clinical test, unmet need in vitro clinical test, and emergency use in vitro clinical test under section 564, the developer may elect to submit the in vitro clinical test under the pathway for any such category or categories.

"(3) APPLICATION CONTENTS.—The developer of an in vitro test seeking approval of the test under this subsection shall submit an application to the Secretary including—

"(A) except as inconsistent with the approval standard specified in paragraph (1), the information described in subsection (d)(2); and

"(B) if such application seeks to demonstrate probable clinical validity under para-

graph (1)(A)(ii), a proposed plan for collection of confirmatory postmarket evidence.

''(4) APPROVAL PROCESS.—

''(A) IN GENERAL.—The Secretary shall—

''(i) issue an order approving or disapproving an application submitted under paragraph (3)—

''(I) in the case of an unmet need in vitro clinical test or rare disease in vitro clinical test, not later than 30 calendar days after the date on which such application is submitted; and

''(II) in the case of an in vitro clinical test described in paragraph (2)(A)(iii), not later than 75 calendar days after the date on which such application is submitted; and

''(ii) in any order disapproving an application, specify the scientific rationale for the disapproval.

''(B) FAILURE TO APPROVE OR DISAPPROVE.—If the Secretary fails to issue an order approving or disapproving an application submitted under paragraph (3) within a time

period applicable under subparagraph (A), the application is deemed to be approved.

''(5) CONFIRMATORY POSTMARKET OBLIGATIONS.—

''(A) AGREED UPON OBLIGATIONS.—If, pursuant to paragraph (1)(A), the Secretary approves an application submitted under paragraph (2) that demonstrates a reasonable assurance that the in vitro clinical test is analytically valid for its intended use and demonstrates probable clinical validity for its intended use without demonstrating a reasonable assurance of clinical validity for its intended use—

''(i) the Secretary shall specify in the order granting such approval the confirmatory postmarket obligations agreed to by the Secretary and the developer of the test; and

''(ii) such confirmatory postmarket obligations—

''(I) shall facilitate the developer's collection of additional valid scientific evidence as necessary to demonstrate a reasonable assurance

that the test is clinically valid for its intended use; and

"(II) may include reporting requirements related to such obligations.

"(B) MODIFICATIONS TO OBLIGATIONS.—The confirmatory postmarket obligations agreed to under subparagraph (A) may be modified at any time by the mutual agreement of the Secretary and the developer.

"(C) LABEL REQUIREMENT.—An order approving an in vitro clinical test under paragraph (1)(A) shall require the labeling of the test to state the following: 'Approved with confirmatory postmarket obligations'.

"(6) LAPSE OF APPROVAL.—

"(A) IN GENERAL.—An approval with confirmatory postmarket obligations under this subsection is deemed to lapse—

"(i) on the date that is three years after such approval unless the developer of the in vitro clinical test submits a supplemental application pursuant to paragraph (7) at least three months prior to such date; or

"(ii) on the date specified in an extension mutually agreed upon by the Secretary and the developer of the in vitro clinical test unless the developer submits a supplemental application pursuant to paragraph (7) at least three months prior to the agreed upon extension date.

"(B) DURATION OF EXTENSION.—The term of any extension described in subparagraph (A)(ii) shall not extend beyond the date that is four years after the date of approval with confirmatory postmarket obligations for the in vitro clinical test.

"(7) SUPPLEMENTAL APPLICATION.—The developer of an in vitro clinical test approved under this subsection subject to confirmatory postmarket obligations may submit a supplemental application to demonstrate a reasonable assurance of clinical validity for the intended use at any time prior to the deadline for submission under paragraph (6).

"(8) DENIAL OF SUPPLEMENTAL APPLICATION.—

"(A) IN GENERAL.—If the Secretary determines that a supplemental application submitted under paragraph (7) does not dem-

onstrate a reasonable assurance of clinical validity for the intended use of the in vitro clinical test—

"(i) the Secretary shall, within 60 calendar days after submission of such application, issue an order disapproving the supplemental application;

"(ii) such order shall specify the scientific rationale for such decision;

"(iii) subject to clause (iv), such decision shall be deemed a withdrawal of the approval under this subsection for the in vitro clinical test; and

"(iv) such decision shall set forth a reasonable timeframe, not to exceed 30 calendar days, after which the developer of the in vitro clinical test shall cease to offer such test

"(B) STAY OF DEADLINES.—A deadline set forth pursuant to subparagraph (A)(iv) shall be stayed during the pendency of an appeal under paragraph (9).

"(9) APPEAL OF DENIAL.—

"(A) IN GENERAL.—Not later than 30 calendar days after the date on which an initial

decision is issued under paragraph (8) denying a supplemental application with respect to an in vitro clinical test, the developer of the test may appeal the denial directly to the Director of the Center for In Vitro Clinical Tests.

''(B) DETERMINATION OF DIRECTOR.—The Director of the Center for In Vitro Clinical Tests shall determine whether to uphold the denial that is the subject of the appeal—

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

''(ii) if the developer requests in the appeal an in-person meeting or teleconference with the Director, not later than 30 calendar days after the date of such meeting or teleconference.

''(C) EFFECT OF DETERMINATION UPHOLDING DENIAL.—If the Director of the Center for In Vitro Clinical Tests upholds a denial of a supplemental application under paragraph (8), such denial shall—

''(i) be deemed to be a withdrawal of the approval for the in vitro clinical test that is the subject of such supplemental application and shall set forth a reasonable

timeframe within which the developer must remove the in vitro clinical test from the market; and

"(ii) shall constitute final action by the Secretary and may not be appealed.

"(10) TERMINATION OF POSTMARKET OBLIGATIONS.—The approval of an in vitro clinical test under paragraph (1)(B) shall continue in effect as described in paragraph (1)(C), and any confirmatory postmarket obligations imposed under this subsection with respect to an in vitro clinical test, including pursuant to the labeling requirement in paragraph (5)(C), shall terminate, if the Secretary—

"(A) determines a supplemental application submitted under paragraph (7) with respect to the test demonstrates a reasonable assurance of clinical validity for the intended use of the test; or

"(B) does not disapprove the supplemental application under paragraph (8) by the deadline applicable under such paragraph.

"(11) WITHDRAWAL OF APPROVAL WITH CONFIRMATORY POSTMARKET OBLIGATIONS.—The Secretary may, after providing notice to the developer of the test and an opportunity for an informal hear-

ing, withdraw an approval of an in vitro clinical test made subject to confirmatory postmarket obligations under this subsection at any time before such approval would otherwise lapse or be withdrawn under this subsection if the Secretary determines, based on new valid scientific evidence, that—

''(A) the developer of the test can no longer demonstrate a reasonable assurance of the analytical validity, and probable clinical validity, of the test for its intended use; or

''(B) the test presents an unreasonable risk to human health.

''(12) PUBLIC DATABASE.—The Secretary may establish a public database that—

''(A) lists each in vitro clinical test approved subject to confirmatory postmarket obligations under this subsection;

''(B) may include, with respect to each such test, the end date and status of such confirmatory postmarket obligations; and

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

''(13) DEFINITIONS.—In this subsection:

"(A) CLINICALLY SIGNIFICANT ADVANTAGE.—The term 'clinically significant advantage' means a reasonable potential to improve the ability to identify, measure, predict, monitor, or assist in selecting treatment for a disease or other condition, including by providing for—

"(i) increased patient access;

"(ii) reduced sample size;

"(iii) expanded sample types;

"(iv) faster diagnosis;

"(v) improved accuracy;

"(vi) less intrusive methods; or

"(vi) other improvements or benefit to patients or public health.

"(B) RARE DISEASE IN VITRO CLINICAL TEST.—The term 'rare disease in vitro clinical test'—

"(i) means an in vitro clinical test intended to identify, measure, predict, monitor, or assist in selecting treatment for a disease or condition with an incidence of 8,000 or fewer per year or a prevalence of 50,000 or fewer in the United States; and

"(ii) excludes an in vitro clinical test intended for the screening of asymptomatic patients or predicting the occurrence of a future disease or condition in asymptomatic patients.

"(C) UNMET NEED IN VITRO CLINICAL TEST.—The term 'unmet need in vitro clinical test' means an in vitro clinical test intended to be used to identify, measure, predict, monitor, or assist in selecting treatment for, a serious or life-threatening disease or condition for which—

"(i) there is no existing in vitro clinical test with the same intended use; and

"(ii) the test could lead to a meaningful improvement in treatment or therapy.

"(g) FALSE STATEMENTS; INCOMPLETE INFORMATION.—The Secretary may—

"(1) disapprove an in vitro clinical test application, or withdraw approval for an in vitro clinical test, if the Secretary finds that—

"(A) the application or listing for such in vitro clinical test under subsection (c), (d), (e), or (f) contains one or more material false statements; and

"(B) after being given an opportunity to correct such statements within a reasonable time, the applicant fails to do so; or

"(2) disapprove an in vitro clinical test application if the Secretary finds that—

"(A) the application for such in vitro clinical test under subsection (c), (d), or (f) fails to include material information that is required to be part of the application; and

"(B) after being given an opportunity to correct such failure within a reasonable time, the applicant fails to do so.

"(h) PREMARKET INSPECTIONS NOT REQUIRED.—The Secretary may not condition the approval of an application under this subchapter on the occurrence of a premarket inspection or manufacturing review related to the application. Nothing in the preceding sentence shall be construed as limiting the authority of the Secretary to conduct quality system inspections under section 704 or other applicable provisions of this Act.

"(i) LABORATORY TEST PROTOCOL TRANSFER OR SALE.—

"(1) LISTING REQUIRED.—An in vitro clinical test that is a laboratory test protocol and approved under subsection (c), (d), (e), or (f) may be trans-

ferred, licensed, or sold to a third party for use pursuant to such approval, so long as, prior to the transfer, licensure, or sale, the party transferring, licensing, or selling the laboratory test protocol submits a supplement to its listing of such laboratory test protocol under subsection (n).

''(2) SHARING AMONG CORPORATE ENTITIES.—The supplemental listing requirement under paragraph (1) does not apply in the case of a transfer, licensure, or sale from an entity to another entity if—

''(A) the first entity controls or has the power to control the other entity;

''(B) the other entity controls or has the power to control the first entity; or

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

''(3) EFFECT OF LABORATORY TEST PROTOCOL TRANSFER.—The transfer, license, or sale of less than the full right, title, and interest in a laboratory test protocol, without transfer or sale of the approval, does not transfer the regulatory obligations of the developer under this subchapter to the transferee, licensee, or purchaser.

''(j) TRANSFER OR SALE OF APPROVAL.—

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

''(2) EFFECT OF APPROVAL TRANSFER.—Upon completion of a transfer or sale described in paragraph (1), the transferee or purchaser shall have the regulatory obligations of the developer of the in vitro clinical test under this subchapter.

''(k) JUSTIFICATION FOR REQUIREMENT TO PROVIDE EVIDENCE FROM CLINICAL TRIALS.—

''(1) WRITTEN JUSTIFICATION FOR MANDATORY CLINICAL TRIAL.—The Secretary shall not require the developer of an in vitro clinical test to submit evidence from a clinical trial as part of any application under this subchapter, unless such application is for approval of a high-risk in vitro clinical test and the Secretary submits to the developer written notice that—

''(A) provides a justification for such requirement, including an explanation of why the Secretary determines that, based on scientific criteria, other evidence is insufficient; and

"(B) is signed by the chief scientific officer of the center for in vitro clinical tests or another member of the senior management of such center.

"(2) WRITTEN JUSTIFICATION FOR OTHER CLINICAL STUDIES.—The Secretary shall not require the developer of an in vitro clinical test to submit evidence from a clinical study other than a clinical trial as part of any application under this subchapter, unless the Secretary submits to the developer written notice that—

"(A) provides a justification for such requirement, including an explanation of why th e Secretary determines that, based on scientific criteria, other evidence is insufficient; and

"(B) is signed by the chief scientific officer of the Center for In Vitro Clinical Tests or another member of the senior management of such center.

"(3) WRITTEN JUSTIFICATION FOR OTHER CLINICAL STUDIES.—The Secretary shall limit the size, scope, and nature of any clinical trial or other clinical study required pursuant to paragraph (1) or (2) to the size, scope, and nature necessary to establish the sufficient evidence not otherwise available,

taking into consideration the feasibility of such clinical trial or other clinical study.

''(4) DEFINITION.—For purposes of this subsection, the term 'clinical trial' means a prospective clinical study comprised of human subjects that is performed to demonstrate clinical validity of the in vitro clinical test versus an established clinical truth, other than the methodologies specified in any of clauses (i) through (ix) of section 590(d)(10)(B).

''(l) GRANDFATHERED TESTS.—

''(1) IN GENERAL.—An in vitro clinical test first offered on a date that occurs before the date that is 90 calendar days prior to the date of enactment of the _____ Act of 2015, and with respect to which the Secretary did not require an approval under section 515, a clearance under section 510(k), or a notification under section 510(j), or otherwise asserted enforcement discretion with regard to such sections and implementing regulations thereunder, is deemed to be approved under this section if the developer—

''(A) lists such in vitro clinical test in accordance with subsection (n)(3)(B); and

''(B) with respect to a non-reviewed, high-risk test, submits to the Secretary, not later

than 4 years after the date of enactment of the _____ Act of 2015, a summary of available analytical validity and clinical validity evidence.

''(2) CONTENTS OF SUMMARY.—A summary required by paragraph (1)(B)—

''(A) need not contain any evidence other than evidence readily available to the developer and shall be provided in summary form; and

''(B) shall not be subject to a user fee under **[**section ____**]**.

''(3) NO ADDITIONAL APPLICATION REQUIRED.—The developer of an in vitro clinical test that is described in paragraph (1) and listed in accordance with subsection (n) need not submit any application for premarket approval of such test under subsection (c), (d), or (f).

''(4) SUBMISSION OF CERTAIN TESTS.—

''(A) IN GENERAL.—The Secretary shall provide written notification to the developer of an in vitro clinical test described in paragraph (1) if, after conducting a literature review and creating a related administrative file, the Secretary determines, based on all available evidence, that such in vitro clinical test—

''(i) presents an unreasonable risk of illness or injury when used as intended by its developer; or

''(ii) is being offered by its developer with materially deceptive or fraudulent analytical or clinical claims.

''(B) MISBRANDING.—Upon receipt of a written notification under subparagraph (A)—

''(i) the developer of an in vitro clinical test may avoid a finding of misbranding by, not later than 120 calendar days after the date on which the developer receives such notification or such later time as agreed to by the developer and the Secretary—

''(I) ceasing to offer such test; or

''(II) submitting a premarket application for such test under subsection (c), (d), or (f) (as applicable); or

''(ii) if the developer fails (by the deadline applicable under clause (i)) to cease offering such test or to submit an application, as described in such clause, or if the Secretary disapproves any applica-

tion so submitted, the test is deemed to be misbranded under section 502.

"(C) APPLICATION CONSIDERATIONS.—In reviewing an application submitted under subparagraph (B)(i)(II), the Secretary shall consider—

"(i) previously unpublished evidence provided by the developer submitting such application; and

"(ii) the developer's description of the past experience with the in vitro clinical test.

"(D) TEMPORARY SALES PERIOD.—During the period of the review of an application submitted under subparagraph (B)(i)(II), the developer submitting such application with respect to an in vitro clinical test may continue to offer the test, without limitation, during the pendency of such submission and if such submission is disapproved, until the date specified by the Secretary.

"(6) DEFINITION.—As used in this subsection, the term 'non-reviewed, high-risk test' means an in vitro clinical test—

"(A) first offered on a date that occurs before the date that is 90 calendar days prior to the date of enactment of the _____ Act of 2015, and with respect to which the Secretary did not require an approval under section 515, a clearance under section 510(k), or a notification under section 510(j) or otherwise asserted enforcement discretion with regard to such sections and implementing regulations thereunder;

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

"(C) which has not been approved by a State pursuant to section 353 of the Public Health Service Act, including the New York State approval process established pursuant to part 58 of title 10 (relating to health) of the Official Compilation of Codes, Rules, and Regulations of the State of New York; and

"(D) which is classified as high-risk pursuant to section 590A(e).

"(m) PREMARKET REQUIREMENTS FOR MODIFICATIONS.—

"(1) IN GENERAL.—A modification to an in vitro clinical test is subject to approval or listing

under subsection (c), (d), (e), or (f) in accordance with the following:

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

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

"(ii) results in a meaningful clinical impact such that the test would be classified as a moderate-risk or high-risk test.

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

"(i) changes the intended use or adds a new intended use that is high-risk or moderate-risk; or

"(ii) results in a meaningful clinical impact.

"(C) In the case of a modification made with respect to a high-risk in vitro clinical test,

the modification is subject to such process only if the modification—

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

"(ii) results in a meaningful clinical impact.

"(2) TREATMENT OF MODIFIED CLASSIFICATION.—In the case of a modification described in paragraph (1), the applicable process for approval or listing of the in vitro clinical test with respect to which the modification is made shall be determined in accordance with the risk classification of the test as so modified, unless validation and verification demonstrate that there is not a meaningful increase in risk to the patient or user for the intended uses compared to the risk assessment for the test as previously approved

"(3) NOTIFICATION.—If the risk assessment for the modification, prior to consideration of verification and validation and considering relevant existing mitigating measures, demonstrates that there is a meaningful and not remote increase in risk to the patient or user for the intended uses compared to the risk assessment for the in vitro clin-

ical test as previously approved, but validation and verification demonstrate that there is not a meaningful increase in risk to the patient or user for the intended uses compared to the risk assessment for the in vitro clinical test as previously approved, the developer of the test shall, not later than the date on which such test is first offered as so modified, submit to the Secretary a notification of such modification. Such notification shall include—

"(A) the name of the in vitro clinical test;

"(B) a brief description of the modification;

"(C) a brief summary of the meaningful and not remote risks identified by the risk assessment described in such paragraph; and

"(D) a brief summary of the validation and verification methodologies or the mitigating measures used with respect to the test, including a brief summary of the results of validation and verifications studies performed with respect to the test.

"(4) EXCEPTION FOR MODIFICATIONS SATISFYING RECOGNIZED STANDARDS.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a premarket application shall not be

required to be submitted under subsection (c), (d), (e), or (f) with respect to a modification to a moderate-risk or high-risk in vitro clinical test if the developer of such test—

"(i) maintains records documenting that the modification satisfies a standard applicable to the modification that is recognized, or contained in guidance issued by, the Secretary and maintains evidence required by the standard; and

"(ii) submits to the Secretary on an annual basis a report summarizing each such modification.

"(B) SPECIMEN-RELATED MODIFICATIONS.—Notwithstanding paragraph (1), a premarket application shall not be required to be submitted under subsection (c), (d), (e), or (f) with respect to a modification to a moderate-risk or high-risk in vitro clinical test if the modification is a specimen-related modification made pursuant to methods and criteria approved or included in a premarket submission for the in vitro clinical test.

"(5) NEW PLATFORMS AND IN VITRO CLINICAL TEST REPLACEMENTS.—

"(A) IN GENERAL.—When an in vitro clinical test has been approved or deemed approved under this section for use on a specific platform that has been approved or deemed approved under this section within a platform family, a submission under subsection (c), (d), or (f) shall not be required for application of that in vitro clinical test to a new platform within that platform family.

"(B) PLATFORM FAMILIES.—A platform is in a platform family if the developer demonstrates and documents internally that the platform and platform family—

"(i) have the same basic design and performance characteristics;

"(ii) have the same intended use and function;

"(iii) share the same measurement principle; and

"(iv) produce a similar analytical result from samples of the same specimen type.

"(6) DETERMINATION ON WHETHER TO MAKE SUBMISSION.—The entity that modifies an in vitro clinical test is the entity responsible for submitting

such modification for any approval or listing required by paragraph (1) and for any related quality system requirements under section 590E.

''(7) SCOPE OF REVIEW.—In reviewing a modification to an in vitro clinical test pursuant to this subsection, the Secretary shall limit the scope of the review to the modification and shall not conduct a de novo review of the overall test.

''(8) DEFINITION OF MEANINGFUL CLINICAL IMPACT.—In this subsection, the term 'meaningful clinical impact' means, with respect to a modification of an in vitro clinical test—

''(A) a modification that changes the diagnosis or therapy delivered to the patient;

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

''(i) introduce new risks not typically associated with the previous indications for use;

''(ii) impact public health to a significantly greater degree than the previous indications for use;

''(iii) are not supported by a body of evidence that reflects an understanding within the medical community that the

changed or additional indications for use are a subset of previous indications for use; or

''(iv) are such that performance characteristics or clinical endpoints established to evaluate the previous indications for use cannot be applied to the changed or additional indications for use;

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

''(D) a modification to a moderate-risk or high-risk in vitro clinical test if the risk assessment for the modification, prior to consideration of verification and validation and considering relevant existing mitigating measures, demonstrates that there is a meaningful and not remote increase in risk to the patient or user for the intended uses, unless validation and verification demonstrate that there is not a meaningful increase in risk to the patient or user for the intended uses compared to the risk

assessment for the test as previously approved; or

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

''(n) LISTING REQUIREMENT.—

''(1) IN GENERAL.—The Secretary shall establish and maintain a list of all in vitro clinical tests approved or otherwise required to be listed under this subchapter.

''(2) PROCESS AND CONTENT OF LISTING.—The list under paragraph (1) shall, with respect to each in vitro clinical test, include—

''(A) the name of the in vitro clinical test;

''(B) the name and contact information of the developer;

''(C) with respect to a laboratory test protocol transferred, licensed, or purchased under subsection (i), the name and contact information of any transferee, licensee, or purchaser

and the completion date of such transfer, license, or purchase;

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

"(E) a summary explanation of the in vitro clinical test.

"(3) PROCESS AND TIMING OF LISTING.—The developer of an in vitro clinical test that is approved or otherwise required to be listed under this subchapter shall submit a notification to the Secretary containing the information described in paragraph (2)—

"(A) in the case of an in vitro clinical test first offered on or after the date that is 180 calendar days after enactment of the _____ Act of 2015, not later than 10 calendar days after the date on which such in vitro clinical test is first offered;

"(B) in the case of an in vitro clinical test that has been first offered before the date that is 180 calendar days after of enactment of the _____ Act of 2015, and which continues to be so offered, not later than 180 calendar days after the date of the enactment of such Act;

"(C) in the case of a laboratory test protocol that is transferred, licensed, or sold under subsection (i), the later of—

"(i) 180 calendar days after enactment of the _____ Act of 2015; or

"(ii) 10 calendar days after the date of such transfer, license, or sale.

"(4) UPDATED LISTING.—The developer of an in vitro clinical test shall submit an updated notification under paragraph (3) on an annual basis.

"(o) REGISTRATION.—

"(1) INITIAL REGISTRATION.—Before the earlier of offering an in vitro clinical test or submitting an application or notification for approval of such a test under this section, the developer of the test shall register with the Secretary and include in such registration—

"(A) the developer's name;

"(B) the developer's place of business; and

"(C) a list of the establishments at which the developer is engaged in the design, development, validation, production, manufacture, preparation, propagation, assembly, or processing of an in vitro clinical test.

''(2) ESTABLISHMENTS WITH GRANDFATHERED IN VITRO CLINICAL TESTS.—Notwithstanding paragraph (1), the developer of an in vitro clinical test described in subsection (l)(1) shall register with Secretary and include in such registration the information listed in paragraph (1) not later than 180 calendar days after the date of enactment of the _____ Act of 2015.

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

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

''(5) INFORMATION CHANGES.—The developer of an in vitro clinical test shall notify the Secretary of any change to the registration information pro-

vided under this subsection not later than 30 calendar days after such change.

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

''(7) REGULATIONS.—The Secretary shall, to the extent possible, harmonize regulations for carrying out this subsection with the corresponding regulations for registration with respect to devices.

''(p) LABELING.—Notwithstanding any provision of this Act—

''(1) an in vitro clinical test may be labeled by electronic means (including by directing health care practitioners and other users to information posted on the Internet) instead of physically affixing the information to the in vitro clinical test;

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

''(A) the first entity controls or has the power to control the other entity;

''(B) the other entity controls or has the power to control the first entity; or

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

''(3) patient test results from the use of an in vitro clinical test or an interpretation of such patient tests results shall not constitute labeling;

''(4) scientific or medical exchanges or discussion regarding one or more in vitro clinical tests shall not constitute labeling;

''(5) communications with actual or potential investors or business partners regarding an unapproved in vitro clinical test or an unapproved intended use of an in vitro clinical test shall not constitute labeling; and

''(6) the developer of a platform shall not make any claims of clinical validity of the platform alone unless such claim is approved by the Secretary.

''SEC. 590C. INVESTIGATIONAL AND RESEARCH USE IN VITRO CLINICAL TESTS.

''(a) IN GENERAL.—Except as provided in subsection (b), an in vitro clinical test for investigational use shall be exempt from the requirements of this subchapter other than sections 590F, 590G, and 590H. Sections 502 and

721, made applicable to in vitro clinical tests by section 590H, shall not apply to such tests.

''(b) APPLICATION FOR AN EXEMPTION.—

''(1) IN GENERAL.—The Secretary shall establish a process under which—

''(A) the Secretary shall require that in the case of an in vitro clinical test the investigational use of which the Secretary determines poses a significant risk to the public health (other than with respect to an investigation for the collection of clinical data through processes other than a prospective clinical trial), a sponsor of an investigation of such a test seeking an exemption under subsection (a) submits to the Secretary an investigational use application with respect to the test in accordance with paragraphs (2) and (3); and

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

''(i) the Secretary shall require that the sponsor of such investigation complies with—

''(I) the requirements specified in paragraphs (3)(A), (3)(B), and (5)(A)(iii); and

''(II) such other requirements as the Secretary may reasonably determine to be necessary for the protection of the public health and safety, including the monitoring of investigations conducted with such test, the establishment and maintenance of records, and the submission to the Secretary of reports of data obtained as a result of the investigational use of the in vitro clinical test during the period covered by the exemption; and

''(ii) the exemptions specified in paragraph (5)(B) and subsection (g) are available with respect to such test.

''(2) APPLICATION CONTENTS.—An investigational use application shall be submitted in such time and manner and contain such information as the Secretary may require, including assurances to the satisfaction of the Secretary that the sponsor involved shall, with respect to the in vitro clinical test that is the subject of the application—

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

''(B) submit to the Secretary 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—

''(C) to ensure compliance with the conditions for approval specified in paragraph (3);

''(D) to review the progress of the investigation involved; and

''(E) to evaluate the analytical validity and clinical validity of such test; and

''(3) CONDITIONS ON APPROVAL.—An investigational use application shall only be approved, if—

''(A) the proposed labeling for the in vitro clinical test involved clearly and conspicuously states 'For investigational use';

''(B) in the case of an application submitted with respect to an in vitro clinical test the clinical testing of which involves human subjects, the sponsor of the investigation—

''(i) if the Secretary has established an institutional review committee estab-

lished by the Secretary to supervise clinical testing of such in vitro clinical tests, submits—

"(I) to such committee a plan that meets the requirements specified in paragraph (5) for any proposed clinical testing of the in vitro clinical test and a report of prior investigations of the test adequate to justify the proposed clinical testing; and

"(II) to the Secretary a summary of such plan and a report of prior investigations; or

"(ii) if no such committee has been so established or the Secretary finds that the process of review by such a committee is inadequate (whether or not the plan for such testing has been approved by such committee), for purposes of beginning clinical testing of the test, submits to the Secretary a plan that meets the requirements specified in paragraph (5) for any proposed clinical testing of the in vitro clinical test and a report of prior investigations of

the test adequate to justify the proposed clinical testing; and

"(C) the sponsor submitting such application provides assurances to the Secretary that the sponsor will comply with such other requirements as the Secretary may reasonably determine to be necessary for the protection of the public health and safety.

"(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)(A)(ii), but only to the extent the requirement with respect to the investigational new drug application is duplicative of the reporting requirement under paragraph (2)(A)(ii).

"(5) INVESTIGATION PLAN REQUIREMENTS.—

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

"(i) in the case of such a plan submitted to an institutional review committee, promptly notify the Secretary, under such circumstances and in such

manner as the Secretary may prescribe, 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 to be distributed or otherwise made available to investigators for clinical testing, obtain, and submit to the Secretary, signed agreements from each of the individuals carrying out the investigation that is the subject of such plan that—

''(I) any testing under such plan involving human subjects will be under the supervision of such individual; and

''(II) the individual will ensure that informed consent is obtained from each such human subject; 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 cases in which, subject

to such other conditions as the Secretary may prescribe—

"(I) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

"(II) the investigator conducting or supervising the proposed clinical testing determines (subject to subparagraph (B)(ii), with the concurrence of a licensed physician who is not involved in the testing of the human subject) in writing that—

"(aa) there exists a life threatening situation involving the human subject of such testing which necessitates the use of such in vitro clinical test;

"(bb) it is not feasible to obtain informed consent from the subject; and

"(cc) there is not sufficient time to obtain such consent from his representative.

"(B) EXCEPTIONS.—

"(i) SIGNED AGREEMENTS NOT REQUIRED FOR AFFILIATES.—Subparagraph (A)(iii) shall not apply to the distribution of or other arrangements by a sponsor to make available an in vitro clinical test to an investigator that is employed by or affiliated with the sponsor.

"(ii) CONCURRENCE OF PHYSICIAN NOT REQUIRED.—The requirement to obtain the concurrence of a licensed physician with respect to a determination under subparagraph (A)(iii) shall not apply if—

"(I) immediate use of the in vitro clinical test in the investigation involved is required to save the life of the human subject; and

"(II) there is not sufficient time to obtain such concurrence.

"(iii) INFORMED CONSENT NOT REQUIRED WITH RESPECT TO CERTAIN SPECIMENS.—Notwithstanding subpara-

graph (A)(iii), the informed consent of human subjects shall not be required to be obtained 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.

''(6) CLASSIFICATION.—If a developer seeks classification of an in vitro clinical test during its investigational use, the Secretary shall use processes and classifications that are consistent with the processes and classifications under section 590A.

''(7) VARIATION OF REQUIREMENTS ALLOWED.—The requirements of this subsection with respect to an investigational use application may vary based on—

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

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

"(C) 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

"(D) 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) REVIEW OF APPLICATIONS.—

"(1) DEEMED APPROVED.—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 (b)(2), issues an order disapproving the application and notifies the sponsor submitting the application of such disapproval, the application shall be deemed approved as of such date.

"(2) DISAPPROVAL.—The Secretary may disapprove an investigational use application submitted under this subsection only if the Secretary determines that the investigation with respect to which the application is submitted does not conform to the requirements of subsection (b)(2). A notification of

such disapproval submitted to the sponsor with respect to such an application shall—

''(A) contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application; and

''(B) provide the sponsor with an opportunity for an informal hearing on the disapproval.

''(d) WITHDRAWAL OF APPROVAL.—

''(1) IN GENERAL.—The Secretary may, by administrative order, withdraw the approval of an exemption granted under this subsection with respect to an in vitro clinical test if the Secretary determines that the test does not meet the applicable conditions under paragraph (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 subsection may be issued after the Secretary provides the 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 be-

fore 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.

''(e) CHANGES OR MODIFICATIONS.—

''(1) IN GENERAL.—The Secretary shall by regulation establish, 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 or modifications to the test are allowed without the additional approval of an application for an exemption or the approval of a supplement to such an application. Such regulations shall provide that such a change or modification may be made if—

''(A) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the change or modification meets the conditions specified in paragraph (2); and

''(B) the sponsor submits to the Secretary, not later than 5 calendar days after making the change or modification, a notice of the change or modification.

''(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; or

''(ii)(I) do not constitute a significant increase in risk to patients; and

''(II) are made in response to information gathered during the course of an investigation; and

''(B) in the case of changes or modifications to clinical protocols applicable to the test, the changes or modifications do not affect—

''(i) the validity of data or information resulting from the completion of an approved clinical protocol, or the relationship of likely patient risk-to-benefit relied upon to approve a clinical protocol;

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

''(iii) the rights, safety, or welfare of the human subjects (if any) involved in the investigation.

''(f) PRE-SUBMISSION MEETING.—

''(1) IN GENERAL.—In the case of a person intending to investigate the clinical validity of a high- or moderate-risk in vitro clinical test, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary under subsection (b)(1), to submit to the Secretary for review an investigational plan (including a clinical protocol).

''(2) REQUEST FOR MEETING.—If the person described in paragraph (1) submits a written request for a meeting with the Secretary regarding the review of an investigational plan described in such paragraph, the Secretary shall, not later than 30 calendar days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan. The written request shall include—

''(A) a detailed description of the in vitro clinical test involved;

''(B) a detailed description of the proposed conditions of use of such test;

"(C) a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of clinical validity or probable clinical validity (as applicable) of, and, if available, information regarding the expected performance from, such test.

"(3) AGREEMENT.—

"(A) REDUCED TO WRITING.—Any agreement under this subsection between the Secretary and a person described in paragraph (1) shall be in writing and part of the administrative record.

"(B) NO AMENDMENTS.— An agreement described in paragraph (1) shall not be changed, except—

"(i) with the written agreement of the person described in such paragraph; or

"(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the center involved in the review, that a substantial scientific issue essential to determining the clinical validity of the in vitro clinical test involved has been identified.

''(C) DECISION BY DIRECTOR.—A decision referred to in subparagraph (B)(ii) shall be in writing, and may be made only after the Secretary has provided to the person described in paragraph (1) an opportunity for a meeting at which the director and such person are present and at which the director documents the scientific issue involved.

''(g) EXEMPTION FROM HUMAN SUBJECT REGULATIONS.—An investigation conducted under an exemption under this section with respect to an in vitro clinical test that involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, is exempt from the rules in part 50 of title 21, Code of Federal Regulations (or any successor regulations), if the information obtained during such investigation is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through personally identifiable information linked to the subjects.

''(h) 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 subparagraph (B). 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 sponsor may immediately appeal any such determination pursuant to section 590F.

''(2) DETERMINATION.—For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that-—

''(A) based on substantial credible evidence, the in vitro clinical test involved presents an unreasonable risk to the safety of the persons who are the subjects of the investigation, taking into account the qualifications of the investigators, information about the in vitro clinical test, the design of the investigation, the condition for which the in vitro clinical test is to be investigated, and the health status of the subjects involved; or

''(B) based on substantial credible evidence, investigator misconduct or sponsor noncompliance with the requirements of this section present an unreasonable risk to the safety of

the persons who are the subjects of the clinical investigation.

''(3) APPEAL.—A sponsor of an investigation may submit to the Secretary a written request that a clinical hold imposed under this subsection be removed. Any such request shall include sufficient information to support the removal of such clinical hold. Not later than 30 calendar days after receipt of such request, the Secretary shall respond to such a request, in writing and, if denying such request, specifying the reasons for such denial.

''(i) DEFINITIONS.—In this section:

''(1) The term 'affiliated' means, with respect to a sponsor, owning the sponsor, owned by the sponsor, under common ownership with the sponsor, or in a joint venture with the sponsor.

''(2) The term 'clinical hold' means an action taken by the Secretary prohibiting the sponsor of an investigation of an in vitro clinical test from conducting the investigation.

''(3) The term 'investigational use application' means, with respect to an in vitro clinical test, an application submitted under subsection (b)(1)(A) for the use of the test by experts qualified by scientific

training and experience to investigate the analytical and clinical validity of the test.

''(4) The term 'serious or life-threatening disease or condition' means a disease or condition—

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

''(B) that results in permanent impairment of a bodily function or permanent damage to a bodily structure within one year unless the course of the disease or condition is interrupted; or

''(C) that necessitates medical or surgical intervention within one year to preclude permanent impairment of a bodily function or permanent damage to a bodily structure.

''(5) The term 'significant risk' means, with respect to an in vitro clinical test that is the subject of an investigational use application, that the investigational use of the test—

''(A) is a use of substantial importance in identifying, measuring, predicting, monitoring, or assisting in selecting treatment for, a serious or life-threatening disease or condition without

confirmation of the diagnosis by a medically established diagnostic product or procedure;

"(B) requires an invasive sampling procedure;

"(C) by design or intention, introduces energy into the human subject;

"(D) otherwise presents a reasonably foreseeable serious risk to the health of a human subject.

"(j) EXCEPTION FOR TESTS USED ONLY IN RESEARCH.—

"(1) RESEARCH-USE-ONLY TESTS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), research-use-only in vitro clinical tests shall not be subject to the requirements of this Act.

"(B) LABELING.—The Secretary shall require that any research-use-only in vitro clinical test be labeled for research use only.

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

"(3) DEFINITIONS.—In this subsection:

"(A) RESEARCH USE ONLY IN VITRO CLINICAL TEST.—The term 'research use only in

vitro clinical test' means an in vitro clinical test that is in the laboratory phase of development.

''(B) BASIC RESEARCH TEST.—The term 'basic research test' means a test that—

''(i) is intended solely for use in the conduct of non-clinical laboratory research, and not for the development of an in vitro clinical test; and

''(ii) is not an in vitro clinical test.

''SEC. 590D. QUALITY REQUIREMENTS; UNIQUE IDENTIFIERS.

''(a) IN GENERAL.—The Secretary shall establish, by regulation, quality requirements for the development and production of in vitro clinical tests (as defined in section 201(ss)) offered under this subchapter. In establishing such requirements, the Secretary shall consider whether to include requirements for each of the following:

''(1) Management responsibility.

''(2) Design controls.

''(3) Document controls.

''(4) Purchasing controls.

''(5) Identification.

''(6) Production and process controls.

''(7) Acceptance activities.

''(8) Nonconforming products.

''(9) Corrective and preventive action.

''(10) Labeling and package controls.

''(11) Handling, storage, distribution, and installation.

''(12) Records.

''(13) Servicing.

''(14) Statistical techniques.

''(b) SCOPE.—The quality requirements under this section shall—

''(1) apply only with respect to the design, development, validation, production, manufacture, preparation, propagation, assembly, or processing of an in vitro clinical test (as defined in section 201(ss)), offered under this subchapter;

''(2) account for differences between in vitro clinical tests that are finished products and in vitro clinical tests that are laboratory test protocols (as such terms are defined in section 201(ss));

''(3) not apply with respect to laboratory operations; and

''(4) not apply to components or parts of an in vitro clinical test or raw materials used in an in vitro clinical test.

''(c) UNIQUE IDENTIFIERS.—

''(1) IN GENERAL.—The Secretary shall promulgate regulations establishing a unique identification system for finished products (as defined in section 201(ss)(3)) requiring the label of finished products to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular finished product.

''(2) REQUIREMENTS.—The unique identifier shall adequately identify the finished product through distribution and use, and may include information on the lot or serial number of the product. The Secretary shall, to the extent possible, harmonize the unique identification system for finished products with, and use tools developed by the Secretary for, the unique device identification system established by the Secretary pursuant to section 519(f). A unique identifier shall not be required for a laboratory test protocol (as defined in section 201(ss)(2)).

''SEC. 590E. POSTMARKET REQUIREMENTS.

''(a) ADVERSE EVENT REPORTING.—

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

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

"(B) include in such records any information, or references to such information, that is in the developer's possession and relates to the adverse event, including documentation of the developer's deliberations used to determine whether an in vitro clinical test error is required to be reported under subparagraph (C) or (F);

"(C) submit to the Secretary a report on an adverse event—

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

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

"(D) include in any report under clause (i) or (ii) of subparagraph (C), as applicable, information regarding—

"(i) the patient;

"(ii) the test;

"(iii) the adverse event;

"(iv) the person who reported the adverse event to the developer;

"(v) the developer; and

"(vi) the laboratory;

"(E) submit to the Secretary a report on all adverse events that are associated with the test and become known to the developer during the preceding quarter of the year, if any; and

"(F) include in any report under subparagraph (E)—

"(i) the number and type of such adverse events which became known to the developer during the quarter covered by the report;

"(ii) trend information regarding adverse events that are associated with the test;

"(iii) aggregated summary information regarding the medical impact of such adverse events on patients, if known; and

"(iv) any newly identified issues or problems relating to the test.

''(2) STATEMENT REQUIRED IN LIEU OF INFORMATION IN CERTAIN QUARTERS.—A report under paragraph (1)(E) for any quarter in which no adverse events occur shall be limited to a statement that no adverse events occurred in such quarter.

''(3) LABORATORY ERRORS.—The developer of an in vitro clinical test shall not be required to maintain records or report under this section regarding laboratory errors that are subject to the standards under section 353(f)(5) of the Public Health Service Act and corrective and preventive actions to address such errors.

''(4) REPORT NOT AN ADMISSION.—A report or other information submitted by a developer or other responsible party under this subsection (and any release by the Secretary of that report or other information) does not constitute an admission by the developer or other responsible party that the in vitro clinical test caused or contributed to an adverse event.

''(5) DEFINITIONS.—In this subsection:

''(A) The term 'adverse event' means—

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

"(ii) any in vitro clinical test error which, if the error were to reoccur, would have a reasonable probability (meaning more than a remote possibility, taking into account the probability of recurrence, existing safeguards, and the probability of resulting harm) of causing death or serious injury.

"(B) The term 'caused by an in vitro clinical test error' means that an in vitro clinical test error was the primary factor in the death of, or serious injury to, a specific patient or user occurring within 1 year of the error.

"(C) The term 'in vitro clinical test error' means a clinically significant failure of an in vitro clinical test to meet its performance specifications or otherwise perform as intended, except that such term excludes any such event or error related to laboratory operations.

"(D) The term 'permanent' means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

"(E) The term 'serious injury' means an injury or illness 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.

"(b) NOTIFICATION.—

"(1) IN GENERAL.—Except with respect to an in vitro clinical test described in section 590B(l)(4), the Secretary may issue such notifications or orders as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health care practitioners who prescribe or use an in vitro clinical test and to any other person (including manufacturers, importers, distributors, retailers, and users (including home users)) who should properly receive such notification, if the Secretary determines that—

"(A) the in vitro clinical test has been offered and presents an unreasonable risk of substantial harm to the public health; and

"(B) 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 such risk,

"(2) ORDERS.—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 notification. That notification shall describe the risk presented by the test and any action which may be taken to eliminate or reduce such risk. Before issuing an order under this subsection, the Secretary shall consult with the persons who are to give notice under the order.

"(c) VOLUNTARY CORRECTIONS AND REMOVALS.—

"(1) IN GENERAL.—A developer or other responsible party may, at any time, initiate a voluntary correction or removal action with respect to an in vitro clinical test.

"(2) NOTICE TO SECRETARY.—Not later than 7 calendar days after the first correction or removal

action undertaken by the developer or other responsible party pursuant to paragraph (1), the developer or other responsible party shall submit to the Secretary, as applicable—

''(A) the name, unique identifier, and other similar information about the in vitro clinical test;

''(B) the name, address, contact information, and registration number of the developer or other responsible party;

''(C) a copy of any customer notification issued by the developer or other responsible party;

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

''(E) a status and summary of the developer or other responsible party's internal investigation;

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

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

''(H) a list of consignees.

''(3) CORRECTION OR REMOVAL IDENTIFIER.—Not later than 7 calendar days after receipt of a notification under paragraph (2), the Secretary shall assign a unique correction or removal identifier to such action and provide such identifier to the developer or other responsible party. The developer or other responsible party shall include such unique identifier on all subsequent correspondence regarding the correction or removal action with the Secretary or any user.

''(4) NOTIFICATION TO USERS.—If communication of a correction or removal action to patients, health care practitioners, and other users is necessary to protect public health, such communication shall include, as applicable—

''(A) the unique correction or removal identifier, as assigned by the Secretary;

''(B) information sufficient to identify the in vitro clinical test subject to the correction or removal;

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

''(D) a description of the potential risks to patients or the public due to the problem, in-

cluding whether injuries or deaths have been associated with the problem;

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

"(F) contact information for obtaining additional information from the developer or other responsible party.

"(5) CLASSIFICATION OF CORRECTION OR REMOVAL.—The Secretary shall classify a correction or removal under this subsection (according to the relative degree of health hazard presented by the in vitro clinical test being corrected or removed) within 30 calendar days of receiving notice pursuant to paragraph (2). If the Secretary determines a notification of such classification in addition to any notification already provided by the developer or other responsible party pursuant to paragraph (4) is necessary to protect public health, the Secretary may issue such notice, and shall include in such notice information clarifying that such notice is intended to inform patients, health care practitioners, and other users that the notice is not a second correction or removal and that the notice is part of an agency

process for classifying an existing correction or removal.

''(6) REPORT NOT AN ADMISSION.—A report or other information submitted by a developer or other responsible party under this subsection (and any release by the Secretary of that report or other information) does not constitute an admission by the developer or other responsible party that the in vitro clinical test caused or contributed to an adverse event..

''(7) CLOSING A CORRECTION OR REMOVAL.—Not later than 45 calendar days after the developer or other responsible party notifies the Secretary that it has completed a correction or removal action, the Secretary shall provide the developer or other responsible party a written statement closing the correction or removal or stating the reasons the Secretary cannot close the correction or removal at that time.

''(d) MANDATORY CORRECTIONS AND REMOVALS.—

''(1) IN GENERAL.—If the Secretary finds that there is a reasonable probability that an in vitro clinical test would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person—

"(A) to immediately cease offering such test; and

"(B) to immediately notify health care practitioners and other users of the in vitro clinical test of the order and to instruct such practitioners and users to cease offering or using such in vitro clinical test.

"(2) INFORMAL HEARING.—An order under paragraph (1) 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 correction or removal 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) AMENDMENT TO REQUIRE CORRECTION OR REMOVAL.—

"(A) AMENDMENT.—If, after providing an opportunity for an informal hearing under paragraph (2), the Secretary determines that an order should be amended to include a correc-

tion or removal of the in vitro clinical test with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a correction or removal. The Secretary shall specify a timetable in which the in vitro clinical test correction or removal will occur and shall require periodic reports to the Secretary describing the progress of the correction or removal.

''(B) CONTENTS.—An amended order under subparagraph (A)—

''(i) shall—

''(I) not include correction or removal of an in vitro clinical test from individuals; and

''(II) not include correction or removal of an in vitro clinical test from in vitro clinical test user facilities if the Secretary determines that the risk of correcting or removing such in vitro clinical test from the facilities presents a greater health risk than the health risk of not correcting or remov-

ing the in vitro clinical test from use; and

"(ii) shall provide for notice to individuals subject to the risks associated with the use of such in vitro clinical test.

"(C) ASSISTANCE OF HEALTH CARE PRACTITIONERS.—In providing the notice required by subparagraph (B)(ii), the Secretary may use the assistance of health care practitioners who prescribed, ordered, or used such an in vitro clinical test for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 705(b).

"(4) CLASSIFICATION.—The Secretary shall classify a correction or removal under this subsection (according to the relative degree of health hazard presented by the in vitro clinical test being corrected or removed) within 30 calendar days of ordering the correction or removal.

"(e) INAPPLICABILITY TO CERTAIN MATTERS.—The Secretary shall not order a notification under subsection (b) or a correction or removal under subsection (d) on the basis of any of the following:

''(1) Changes or improvements in laboratory operations.

''(2) Corrections or updates to patient-specific laboratory reports.

''(3) Enhancements to an in vitro clinical test.

''(f) POSTMARKET SURVEILLANCE.—

''(1) IN GENERAL.—The Secretary may by order require a developer to conduct postmarket surveillance, including postmarket studies, for an approved high-risk or moderate-risk in vitro clinical test only if the Secretary determines, based on new valid scientific evidence, that the failure of such in vitro clinical test would be reasonably likely to have serious adverse health consequences.

''(2) POSTMARKET CLINICAL TRIALS.—The Secretary may require the developer of an in vitro clinical test to conduct a postmarket clinical trial under paragraph (1) only for a high-risk in vitro clinical test and only if the Secretary determines that no other approach can provide the necessary information. The authority to require such a trial shall not be delegated to any official or employee below the level of senior management of the Center for in vitro clinical tests.

''(g) MISBRANDED IN VITRO CLINICAL TESTS.—An in vitro clinical test shall be deemed to be misbranded if the Secretary finds, based on all available data and information, that the in vitro clinical test presents an unreasonable and substantial risk of illness or injury when used as intended by its developer.

''SEC. 590F. APPEALS.

''(a) IN GENERAL.—The Secretary shall establish by regulation an appeals process for the review of classification and reclassification determinations under section 590A, premarket determinations under sections 590B and 590C, and other adverse decisions made by the Secretary under this subchapter. Except as otherwise provided in this subchapter, the process established by the Secretary shall be consistent with the guidance entitled 'Center for Devices and Radiological Health Appeals Processes' and dated May 17, 2013.

''(b) FINAL ACTION FOR JUDICIAL REVIEW.—In all cases, the process established under subsection (a) shall provide for a decision constituting final action by the agency not later than 180 calendar days after the date on which the appeal is first submitted.

''(b) ADVISORY PANELS.—The appeal process established under subsection (a) shall permit the appellant to request review by an advisory panel. Any such advisory

panel shall include interested persons with knowledge of in vitro clinical tests, laboratory operations, and the use of in vitro clinical tests.

"SEC. 590G. 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 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. 590H. APPLICABILITY OF CERTAIN PROVISIONS.

"The provisions of sections 301, 303(f)(1), 304, 306, 501, 502, 503(a), 503(g), 506, 509, 517 , 520(c), 561,

562, 563, 566(b), 566(e), 702, 703, 705, 721, 756, 770, 801, 802, 803, 1003, 1003a, and 1011 apply with respect to in vitro clinical tests to the same extent and in the same manner as such provisions apply with respect to devices, except as follows:

"(1) Such provisions apply with respect to in vitro clinical tests only to the extent such provisions are determined by the Secretary to be consistent with this subchapter.

"(2) The following provisions do not apply with respect to in vitro clinical tests: Section 301(y), subsections (e), (f), (g), (h), and (i) of section 501, subsections (q), (r), (s), (t)(2), and (t)(3) of section 502, and section 510.

"(3) In the case of in vitro clinical tests, the statement required by section 502(v) is '"Reprocessed in vitro clinical test for single use. Reprocessed by ____."'.

"(4) In applying section 503(g)(1)(B), if the Secretary determines that the primary mode of action is that of an in vitro clinical test, the agency center charged with premarket review of in vitro clinical tests shall have primary jurisdiction.".

(b) CONFORMING AMENDMENT.—Section 517(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a)) is amended—

(1) by striking ''or'' at the end of paragraph (8);

(2) by inserting ''or'' at the end of paragraph (9); and

(3) by inserting after paragraph (9) the following:

''(10) the issuance of a decision under section 590F,''.

(c) EMERGENCY USE OF IN VITRO CLINICAL TESTS.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended—

(1) in subsections (a)(1) and (a)(4)(C), by inserting ''in vitro clinical test,'' before ''or biological product'' each place it appears;

(2) in paragraph (2) of subsection (b), by adding at the end the following:

''(C) CONTINUED PRODUCT AVAILABILITY AFTER TERMINATION.—A manufacturer or provider of an in vitro clinical test with an authorization under this section may consult with the Secretary for, and the Secretary may allow, continued distribution and use of such test after

termination of the authorization if the conditions of subsections (c)(2), (c)(3), and (c)(4) continue to be satisfied.'';

(3) in subsection (c), in the matter before paragraph (1), by inserting ''(and with respect to in vitro clinical tests local, State, or regional public health authorities)'' after ''the Director of the Centers for Disease Control and Prevention'';

(4) in subsection (e)(3)—

(A) in subparagraph (A), by inserting ''design (with respect to in vitro clinical tests),'' before ''manufacture,''; and

(B) in subparagraph (B), by striking ''and'' at the end;

(C) in subparagraph (C), by striking the period at the end and inserting ''; and''; and

(D) by adding at the end the following:

''(D) quality system requirements (with respect to laboratories and laboratory operations) established under section 353 of the Public Health Service Act.'';

(5) in subsection (f)(2), by inserting ''or, in the case of an in vitro clinical test, for diagnosis, prognosis, or monitoring'' before ''to the extent''; and

(6) in subsection (m)—

(A) in the subsection heading, by striking ''LABORATORY TESTS ASSOCIATED WITH DEVICES'' and inserting ''IN VITRO CLINICAL TESTS''; and

(B) in paragraph (1)—

(i) by striking ''a device'' and inserting ''an in vitro clinical test''; and

(ii) by striking ''such device'' and inserting ''such in vitro clinical test''.

(d) INSPECTIONS.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended by adding at the end the following:

''(h) INSPECTIONS BY ACCREDITED PERSONS.—

''(1) IN GENERAL.—The Secretary shall establish by regulation a process to accredit persons for the purpose of conducting inspections of establishments engaged in the design, development, validation, production, manufacture, preparation, propagation, assembly, or processing of an in vitro clinical test. The process established by the Secretary shall permit the owner or operator of such an establishment to select, from the list published under paragraph (4), an accredited person to conduct such inspections.

''(2) ACCREDITATION CRITERIA.—The Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1).

''(3) DISPOSITION OF REQUESTS FOR ACCREDITATION.—The Secretary shall—

''(A) not later than 60 calendar days after the receipt of a request for accreditation under this subsection, inform the requesting person whether the request is adequate for review; and

''(B) promptly accredit or deny accreditation to the person.

''(4) LIST.—The Secretary shall—

''(A) publish on the Internet site of the Food and Drug Administration a list of persons who are accredited under this subsection; and

''(B) keep such list updated to ensure that the identity of each accredited person, and the particular activities for which the person is accredited, is available to the public.

''(i) HYBRID INSPECTIONS.—

''(1) INTERAGENCY AGREEMENT.—The Commissioner of Food and Drugs may enter into an agreement with the Administrator of the Centers for

Medicare & Medicaid Services to jointly train and accredit hybrid inspectors authorized to inspect—

"(A) establishments engaged in the design, development, validation, production, manufacture, preparation, propagation, assembly, or processing of an in vitro clinical test pursuant to subchapter J of chapter V; and

"(B) laboratories operating under section 353 of the Public Health Service Act

"(2) REQUIREMENTS.—A hybrid inspector conducting an inspection pursuant to an agreement under subparagraph (A) shall—

"(A) prior to such inspection, state whether the hybrid inspector intends to conduct an inspection pursuant to subchapter J of chapter V, section 353(g)(1) of the Public Health Service Act, or both;

"(B) conduct any inspection in accordance with the intent stated under clause (i); and

"(C) with respect to an establishment that is both engaged in the design, development, validation, production, manufacture, preparation, propagation, assembly, or processing of an in vitro clinical test and operating as a laboratory, if the inspector intends to inspect such estab-

lishment pursuant to both subchapter J of chapter V and section 353(g)(1) of the Public Health Service Act, notify such establishment or laboratory of such intent and maintain a clear distinction between the portions of such inspection conducted pursuant to such subchapter J and the portions of such inspection conducted pursuant to such section 353(g)(1).

''(3) UNEXPECTED ISSUES.—If during the course of an inspection for which the stated intent is to conduct an inspection pursuant to subchapter J of chapter V, a hybrid inspector identifies one or more issues under section 353 of the Public Health Service Act, the hybrid inspector shall—

''(A) notify the establishment or laboratory of the issues and, at the discretion of the inspector, notify the Centers for Medicare & Medicaid of the issues; and

''(B) in collaboration with the Centers for Medicare & Medicaid, determine whether such notice warrants other action under such section 353.''.

(e) REGULATIONS.—

(1) PROMULGATION.—Not later than 2 years after the date of enactment of this Act, the Sec-

retary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall promulgate final regulations to carry out the amendments made by this section.

(2) EFFECTIVE DATE.—

(A) IN GENERAL.—The regulations promulgated pursuant to paragraph (1) shall take effect on the date that is 2 years after the date of such promulgation.

(B) PREMARKET REQUIREMENTS.—Notwithstanding subparagraph (A), with respect to a manufacturer (as defined in section 7), the regulations promulgated pursuant to paragraph (1) to carry out sections 590A, 590B, and 590C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall take effect on the date that is 1 year after the date of such promulgation.

(3) FINISHED PRODUCTS AND LABORATORY TEST PROTOCOLS.—All regulations established pursuant to paragraph (1) shall account for differences between finished products and laboratory test protocols (as such terms are defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by section 2(a)).

(f) EDUCATION AND TRAINING OF AGENCY EMPLOYEES AND CONTRACTORS.—

(1) ESTABLISHMENT OF PLAN.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(A) publish a proposed plan for education and training of employees and contractors of the Food and Drug Administration on implementation of the amendments made by this section;

(B) provide an opportunity for public comment on such plan during a period of not less than 90 calendar days;

(C) not later than 2 years after the date of enactment of this Act, publish a final version of such plan; and

(D) ensure that initial training of employees and contractors under the plan is completed within 1 year of the date of publishing such final version.

(2) PLAN CONTENTS.—The plan required by paragraph (1) shall include—

(A) detailed plans for rigorous ongoing and initial training of employees and contractors of the Food and Drug Administration on imple-

mentation of the amendments made by this section, including the standard for review, approval, and listing of an in vitro clinical test under section 590B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

(B) education of such employees and contractors on the operation of clinical laboratories and the scope of activities within such laboratories that are subject to regulation under such amendments; and

(C) ongoing training of such employees and contractors on the technology and utilization of in vitro clinical tests.

(g) ANNUAL REPORT.—Not later than one year after the date of enactment of this Act, and annually thereafter, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit a report to the Congress—

(1) describing activities that have been undertaken by the Food and Drug Administration pursuant to the amendments made by this section and progress toward relevant statutory deadlines;

(2) explaining the ways in which such activities account for the unique characteristics of in vitro

clinical tests and differ from the regulation of devices; and

(3) explaining the ways in which such activities promote patient access to new in vitro clinical tests.

(h) EXECUTIVE PERFORMANCE.—Timely and appropriate implementation and execution of this Act shall be included in the performance evaluations of relevant Food and Drug Administration executives, including members of the Senior Executive Service and equivalent positions, for purposes of determining any performance bonus, salary increase, or job advancement.

[SEC. 4. FDA FEES.

[*to be supplied***]]**

SEC. 5. CERTIFICATION OF LABORATORIES (CLIA).

Section 353 of the Public Health Service Act (42 U.S.C. 263a) is amended to read as follows:

"SEC. 353. CERTIFICATION OF LABORATORIES.

"(a) SCOPE OF AUTHORITY; DEFINITIONS.—

"(1) SCOPE OF AUTHORITY.—Laboratories shall be regulated by the Secretary under this section. Laboratory operations shall be regulated by the Secretary under this section and shall not be regulated under the Federal Food, Drug, and Cosmetic Act.

"(2) LIMITATIONS OF AUTHORITY.—

"(A) FDA REGULATION.—The design, development, validation, production, manufacture, preparation, propagation, assembly, and processing of an in vitro clinical test shall be regulated under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, and shall not be regulated by the Secretary under this section.

"(B) OTHER ACTIVITIES.—The Secretary shall not regulate the practice of medicine under this section. The authority to so regulate shall be reserved to the individual States.

"(3) DEFINITIONS.—In this section:

"(A) The term 'certificate' refers, as applicable, to—

"(i) the documentary evidence of authorization to engage in the activities regulated in this section required under subsection (b); or

"(ii) a certificate of waiver issued under subsection (d)(2).

"(B) The term 'in vitro clinical test' has the meaning given to that term in section 201(ss) of the Federal Food, Drug, and Cosmetic Act.

''(C) The term 'laboratory' or 'clinical laboratory' means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

''(D)(i) The term 'laboratory operations' means the conduct of an in vitro clinical test and associated activities not excluded by paragraph (a)(1)(B) from the Secretary's authority to regulate under this section, within or under the oversight of a laboratory. Such term includes the following activities:

''(I) Developing and implementing standard operating procedures.

''(II) Verifying laboratory performance of an in vitro clinical test.

''(III) Performing pre-analytical processes for an in vitro clinical test.

''(IV) Collection, transportation, disposition, and storage of patient specimens.

''(V) Preparing reagents or other test materials which do not meet the definition of a finished test product under section 201(ss) of the Federal Food, Drug, and Cosmetic Act.

''(VI) Performing an in vitro clinical test pursuant to the relevant standard operating procedures for such test.

''(VII) Reporting the output or results of an in vitro clinical test.

''(VIII) Validating modifications to in vitro clinical tests if such modifications are not regulated under subchapter J of the Federal Food, Drug, and Cosmetic Act.

''(ii) Such term includes the preparation and transfer of individual components, parts, and raw materials between commonly owned laboratories within the same State, if—

''(I) the Secretary has established by regulation—

''(aa) applicable quality requirements that are substantially equivalent to the comparable quality requirements under subchapter J of the Federal Food, Drug and Cosmetic Act;

''(bb) inspection processes that are substantially equivalent to the comparable inspection processes under such subchapter J; and

''(cc) enforcement processes that are substantially equivalent to the comparable enforcement processes under such subchapter J;

''(II) the Secretary reviews the regulations established pursuant to subclause (I) three years after the effective date of such regulations to determine whether comparable quality requirements are being implemented as required by such clause and whether the value of such requirements are commensurate with the related burden; and

''(III) as part of the review conducted pursuant to subclause (II), the Secretary—

''(aa) holds at least one public meeting;

''(bb) issues a draft determination regarding whether to maintain or amend the quality requirements established pursuant to subclause (I);

"(cc) provides for a public comment period of 90 days on the draft determination; and

"(dd) issues a final determination, with any proposed amended regulations, not later than four years after the effective date of the regulations established pursuant to subclause (I).

"(E) The term 'standard operating procedures' means instructions for implementation of one or more in vitro clinical tests, in one or more laboratories, that do not materially alter the design, development, validation, production, manufacture, preparation, propagation, assembly, or processing of such in vitro clinical tests.

"(b) CERTIFICATE REQUIREMENT.—No person may solicit or accept materials derived from the human body for laboratory examination or other laboratory procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

"(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

''(1) IN GENERAL.—The Secretary may issue or renew a certificate for a laboratory only if the laboratory meets the requirements of subsection (d).

''(2) TERM.—A certificate issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

''(d) REQUIREMENTS FOR CERTIFICATES.—

''(1) IN GENERAL.—A laboratory may be issued a certificate or have its certificate renewed if—

''(A) the laboratory submits (or if the laboratory is accredited under subsection (e), the accreditation body which accredited the laboratory submits), an application—

''(i) in such form and manner as the Secretary shall prescribe;

''(ii) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory including—

''(I) the number and types of laboratory examinations and other procedures performed;

''(II) the methodologies for laboratory examinations and other procedures employed; and

"(III) the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures; and

"(iii) that contains such other information as the Secretary may require to determine compliance with this section; and

the laboratory agrees to provide to the Secretary (or if the laboratory is accredited, to the accreditation body which accredited it) a description of any change in the information submitted under clause (ii) not later than 6 months after the change was put into effect;

"(B) the laboratory provides the Secretary—

"(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f); or

"(ii) with proof of accreditation under subsection (e);

"(C) the laboratory agrees to permit inspections by the Secretary under subsection (g);

''(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may reasonably require;

''(E) the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business, except that no proficiency testing sample shall be intentionally referred to another laboratory for analysis as prohibited under subsection (i)(4); and

''(F) the laboratory has in place processes and policies to review and assess modifications to in vitro clinical tests, as required by paragraph (4).

''(2) REQUIREMENTS FOR CERTIFICATES OF WAIVER.—

''(A) IN GENERAL.—A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be issued a certificate of waiver or have its certificate of waiver renewed if—

''(i) the laboratory submits an application—

''(I) in such form and manner as the Secretary shall prescribe;

''(II) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory, including the number and types of laboratory examinations and other procedures performed, the methodologies for laboratory examinations and other procedures employed, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures; and

''(III) that contains such other information as the Secretary may reasonably require to determine compliance with this section; and

''(ii) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require.

''(B) CHANGES THAT MAY AFFECT WAIVED STATUS.—

''(i) CHANGES TO CERTAIN EXAMINATIONS AND PROCEDURES.—If a laboratory makes changes in the examinations and other procedures performed by it only with respect to examinations and procedures which are described in paragraph (3), the laboratory shall report such changes to the Secretary not later than 6 months after the change has been put into effect.

''(ii) OTHER CHANGES.—If a laboratory proposes to make changes in the examinations and procedures performed by it such that the laboratory will perform an examination or procedure not described in paragraph (3), the laboratory shall report such change to the Secretary before the change takes effect. The laboratory shall report any such change to the Secretary without regard to whether such change is a modification subject to premarket approval under section 590B(m) of the Federal Food, Drug, and Cosmetic Act. If any such change is a modification subject to premarket approval under such section 590B(m), the laboratory shall obtain such

approval before putting the modification into effect.

''(iii) HIGH COMPLEXITY.— In the case of any modification by a laboratory to an examination or procedure described in paragraph (3) that causes the examination or procedure to have high complexity, the examination or procedure shall be subject to the requirements under this section for high complexity examinations and procedures.

''(C) EFFECT.—Subsections (g) and (h) shall not apply to a laboratory to which a certificate of waiver has been issued.

''(3) EXAMINATIONS AND PROCEDURES.—

''(A) IN GENERAL.—The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

"(i) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible; or

"(ii) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.

"(B) DEFINITION.—In this paragraph, the phrase 'accurate as to render the likelihood of erroneous results by the user negligible' means, with respect to an in vitro clinical test, that the accuracy achieved by individuals qualified to perform a laboratory examination or procedure in a laboratory holding a certificate of waiver under paragraph (2) is equivalent to the accuracy achieved by individuals qualified to perform a laboratory examination or procedure in a laboratory certified under paragraph (1), as shown by evidence that directly compares such accuracy or evaluates such agreement of results.

"(e) ACCREDITATION.—

"(1) IN GENERAL.—A laboratory may be accredited for purposes of obtaining a certificate if the laboratory—

''(A) meets the standards of an approved accreditation body; and

''(B) authorizes the accreditation body to submit to the Secretary (or such State agency as the Secretary may designate) such records or other information as the Secretary may require.

''(2) APPROVAL OF ACCREDITATION BODIES.—

''(A) IN GENERAL.—The Secretary may approve a State's laboratory licensure program, or a private nonprofit organization, to be an accreditation body for the accreditation of laboratories if—

''(i) using inspectors qualified to evaluate the methodologies used by the laboratories in performing laboratory examinations and other procedures, the accreditation body agrees to inspect a laboratory for purposes of accreditation with such frequency as may be determined by the Secretary;

''(ii) the standards applied by the body in determining whether or not to accredit a laboratory are the standards issued by the Secretary under subsection (f);

''(iii) there is adequate provision for assuring that the standards issued by the Secretary under subsection (f) continue to be met by the laboratory;

''(iv) in the case of any laboratory accredited by the body which has had its accreditation denied, suspended, withdrawn, or revoked or which has had any other action taken against it by the accrediting body, the accrediting body agrees to submit to the Secretary the name of such laboratory within 30 days of the action taken; and

''(vi) if the accreditation body has its approval withdrawn by the Secretary, the body agrees to notify each laboratory accredited by the body of the withdrawal within 10 days of the withdrawal.

''(B) CRITERIA AND PROCEDURES.—The Secretary shall promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval if the Secretary determines that the accreditation body does not meet the requirements of subparagraph (A).

"(C) EFFECT OF WITHDRAWAL OF APPROVAL.—If the Secretary withdraws the approval of an accreditation body under subparagraph (B), the certificate of any laboratory accredited by the body shall continue in effect for 60 calendar days after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if the Secretary determines that the laboratory submitted an application for accreditation or a certificate in a timely manner after receipt of the notification of the withdrawal of approval.

"(D) EVALUATIONS.—The Secretary shall evaluate annually the performance of each approved accreditation body by—

"(i) inspecting under subsection (g) a sufficient number of the laboratories accredited by such body to allow a reasonable estimate of the performance of such body; and

"(ii) such other means as the Secretary determines appropriate.

"(3) WITHDRAWAL OR REVOCATION OF LABORATORY ACCREDITATION.—If an accreditation body

withdraws or revokes the accreditation of a laboratory, the certificate of the laboratory shall continue in effect—

"(A) for 45 calendar days after the laboratory receives notice of the withdrawal or revocation of the accreditation; or

"(B) until the effective date of any action taken by the Secretary under subsection (j).

"(4) UPDATED STANDARDS.—Approved accreditation bodies shall ensure that, beginning no later than the effective date of the standards under subsection (f)(5) and the regulations for carrying out such standards—

"(A) the inspectors of such bodies are trained with respect to, and the processes of such bodies are updated in accordance with, such regulations; and

"(B) any inspection or other review of a laboratory by the approved accreditation body for purposes of accreditation includes a review and assessment of—

"(i) compliance by the laboratory with such regulations; and

"(ii) whether sufficient processes, policies, organization, and training systems

are in place to demonstrate reasonable assurance of future compliance with such regulations.

''(f) STANDARDS.—

''(1) IN GENERAL.—The Secretary shall issue standards to assure consistent performance by laboratories issued a certificate under this section of valid and reliable laboratory examinations and other procedures. Such standards shall require each laboratory issued a certificate under this section—

''(A) to maintain a quality system for all phases of the total testing process (consisting of the pre-analytic, analytic, and post-analytic processes) and general laboratory systems adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and the reporting of results;

''(B) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory;

''(C) in performing and carrying out its laboratory examinations and other procedures,

to use only personnel meeting such qualifications as the Secretary may establish for the direction, supervision, and performance of examinations and procedures within the laboratory, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications shall, as appropriate, be different on the basis of the type of examinations and procedures being performed by the laboratory and the risks and consequences of erroneous results associated with such examinations and procedures;

''(D) to qualify under a proficiency testing program meeting the standards established by the Secretary under paragraph (3);

''(E) to have in place change control procedures assessing the impact of changes in laboratory operations, equipment, or material on the validity and reliability of the examinations and other procedures of the laboratory;

''(G) to have in place quality systems to assess the ability of incoming materials and equipment to meet their intended purposes;

"(H) to meet such other requirements as the Secretary reasonably determines necessary to assure consistent performance by such laboratories of valid and reliable laboratory examinations and procedures; and

"(I) to have in place processes and policies to review and assess modifications to in vitro clinical tests in accordance with paragraph (7).

"(2) CONSIDERATIONS.—In developing the standards to be issued under paragraph (1), the Secretary shall, within the flexibility provided under subparagraphs (A) through (H) of paragraph (1), take into consideration—

"(A) the examinations and procedures performed and the methodologies employed;

"(B) the degree of independent judgment involved;

"(C) the amount of interpretation involved;

"(D) the difficulty of the calculations involved;

"(E) the calibration and quality control requirements of the instruments used;

"(F) the type of training required to operate the instruments used in the methodology;

"(G) the regulations issued by the Secretary to carry out subchapter J of the Federal Food, Drug, and Cosmetic Act, in order to avoid duplicative requirements; and

"(H) such other factors as the Secretary considers relevant.

"(3) PROFICIENCY TESTING PROGRAM.—

"(A) IN GENERAL.—The Secretary shall establish standards for the proficiency testing programs for laboratories issued a certificate under this section which are conducted by the Secretary, conducted by an organization approved under subparagraph (C), or conducted by an approved accrediting body. The standards shall require that a laboratory issued a certificate under this section be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed. The testing shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or

procedure may be tested less frequently (but not less often than twice per year). Such standards shall include standards for proficiency testing programs for the new specialties and subspecialties identified under paragraph (5)(iii).

''(B) CRITERIA.—The standards established under subparagraph (A) shall include uniform criteria for acceptable performance under a proficiency testing program, based on the available technology and the clinical relevance of the laboratory examination or other procedure subject to such program. The criteria shall be established for all examinations and procedures and shall be uniform for each examination and procedure. The standards shall also include a system for grading proficiency testing performance to determine whether a laboratory has performed acceptably for a particular quarter and acceptably for a particular examination or procedure or category of examination or procedure over a period of successive quarters.

''(C) APPROVED PROFICIENCY TESTING PROGRAMS.—For the purpose of administering proficiency testing programs which meet the standards established under subparagraph (A),

the Secretary shall approve a proficiency testing program offered by a private nonprofit organization or a State if the program meets the standards established under subparagraph (A) and the organization or State provides technical assistance to laboratories seeking to qualify under the program. The Secretary shall evaluate each program approved under this subparagraph annually to determine if the program continues to meet the standards established under subparagraph (A) and shall withdraw the approval of any program that no longer meets such standards.

''(D) ONSITE TESTING.—The Secretary shall perform, or shall direct a program approved under subparagraph (C) to perform, onsite proficiency testing to assure compliance with the standards under this section, in accordance with paragraph (5). The Secretary shall perform, on an onsite or other basis, proficiency testing to evaluate the performance of a proficiency testing program approved under subparagraph (C) and to assure quality performance by a laboratory.

''(E) TRAINING, TECHNICAL ASSISTANCE, AND ENHANCED PROFICIENCY TESTING.—The Secretary may, in lieu of or in addition to actions authorized under subsection (i), (j), or (k), require any laboratory which fails to perform acceptably on an individual examination and procedure or a category of examinations and procedures—

''(i) to undertake training and to obtain the necessary technical assistance to meet the requirements of the proficiency testing program;

''(ii) to enroll in a program of enhanced proficiency testing; or

''(iii) to undertake any combination of the training, technical assistance, or testing described in clauses (i) and (ii).

''(F) TESTING RESULTS.—The Secretary shall establish a system to make the results of the proficiency testing programs subject to the standards established by the Secretary under subparagraph (A) available, on a reasonable basis, upon request of any person. The Secretary shall include with results made available under this subparagraph such explanatory in-

formation as may be appropriate to assist in the interpretation of such results.

''(4) NATIONAL STANDARDS FOR QUALITY ASSURANCE IN CYTOLOGY SERVICES.—

''(A) ESTABLISHMENT.—The Secretary shall establish national standards for quality assurance in cytology services designed to assure consistent performance by laboratories of valid and reliable cytological services.

''(B) STANDARDS.—The standards established under subparagraph (A) shall include—

''(i) the maximum number of cytology slides that any individual may screen in a 24-hour period;

''(ii) requirements that a clinical laboratory maintain a record of—

''(I) the number of cytology slides screened during each 24-hour period by each individual who examines cytology slides for the laboratory; and

''(II) the number of hours devoted during each 24-hour period to screening cytology slides by such individual;

''(iii) criteria for requiring rescreening of cytological preparations, such as—

''(I) random rescreening of cytology specimens determined to be in the benign category;

''(II) focused rescreening of such preparations in high risk groups; and

''(III) for each abnormal cytological result, rescreening of all prior cytological specimens for the patient, if available;

''(iv) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions;

''(v) procedures for detecting inadequately prepared slides, for assuring that no cytological diagnosis is rendered on such slides, and for notifying referring physicians of such slides;

''(vi) requirements that all cytological screening be done on the premises of a laboratory that is certified under this section;

''(vii) requirements for the retention of cytology slides by laboratories for such periods of time as the Secretary considers appropriate; and

''(viii) standards requiring periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.

''(5) UNIFORMITY; SPECIALTIES AND SUBSPECIALTIES; ERRORS; HARMONIZATION.—

''(A) IN GENERAL.—The Secretary shall ensure that the standards under this subsection—

''(i) provide nationally uniform standards for the performance of laboratory operations;

''(ii) include—

''(I) standards for specialty and subspecialty testing, including with respect to molecular pathology, molecular microbiology, biochemical genetics, and flow cytometry testing and

other specialty and subspecialty testing not specifically included as of the date of enactment of the _____ Act of 2015 in existing regulations and standards; and

''(II) updated standards for cytogenetics, microbiology, and other appropriate specialties and subspecialties;

''(iii) include common standards for the identification, investigation, and assessment of laboratory errors and for the corrective and preventive actions appropriate to address such errors;

''(iv) include enhanced quality requirements for preparation of reagents for use not as a finished product but as a component, part, or raw material of an in vitro clinical test performed by the same facility, and for preparation and transfer of individual components, parts, and raw materials between commonly owned laboratories within the same State, to ensure consistent reagent preparation and quality control of the reagent; and

"(v) to the extent possible, be harmonized, in cooperation with the Food and Drug Administration and the Centers for Medicare & Medicaid Services, with other existing standards and best practices, including the accreditation standards of widely recognized professional organizations and the terms, definitions, and standards under section 590E of the Federal Food, Drug and Cosmetic Act

"(B) QUALITY SYSTEM PROCESSES.—The standards under this subsection shall include quality assurance processes for—

"(i) management responsibility and authority;

"(ii) document controls;

"(iii) purchasing controls;

"(iv) laboratory process and operation quality systems and controls;

"(v) corrective and preventive actions;

"(vi) records; and

"(vii) servicing.

"(C) MODERNIZED REGULATIONS.—Not later than the day that is 2 years after the date of enactment of the _____ Act of 2015, the

Secretary shall issue final regulations to implement this paragraph.

''(D) EFFECTIVE DATE.—The final regulations required to be issued under subparagraph (C) shall take effect on the date that is 2 years after the date of issuance of such final regulations. On and after such effective date—

''(i) the Secretary may issue or renew a certificate for a laboratory under this section only if the laboratory is in compliance with such regulations and standards; and

''(ii) each laboratory required to be certified under this section shall comply with such regulations.

''(6) ADVISORY PANEL.—In proposing and finalizing regulations under paragraph (5), the Secretary shall utilize an advisory panel to provide input into the development and content of such regulations. Such advisory panel shall include, at a minimum, representatives of laboratories, laboratory operations experts, health care professionals, professional societies, patient groups, laboratory test developers, regulatory and quality experts, and public health experts.

"(7) MODIFICATIONS TO IN VITRO CLINICAL TESTS.—

"(A) PROCESSES AND POLICIES.—A laboratory shall have in place processes and policies to review and assess modifications to in vitro clinical tests prior to the implementation of such a modification within laboratory operations. Such a review and assessment shall be designed to determine whether the proposed modification results in a meaningful clinical impact or changes the intended use of the in vitro clinical test so as to be subject to premarket approval or listing under section 590B(m) of the Federal Food, Drug, and Cosmetic Act.

"(B) PREMARKET APPROVAL OR LISTING.—If the proposed modification has a meaningful clinical impact or changes the intended use of the in vitro clinical test so as to be subject to premarket approval or listing under section 590B(m) of the Federal Food, Drug, and Cosmetic Act, the laboratory—

"(i) shall obtain an approval pursuant to Section 590B of the Federal Food, Drug, and Cosmetic Act or, if such an approval is not required, shall list such modi-

fication pursuant to section 590B(e) of the Federal Food, Drug, and Cosmetic Act; and

''(ii) shall not implement such modification until such approval is obtained or listing occurs, as applicable.

''(C) EXCLUSIONS.—Amendments, changes, corrections, or updates to a patient specific laboratory test report—

''(i) shall not be considered a modification that requires review under section 590B(m) of the Federal Food, Drug, and Cosmetic Act; and

''(ii) shall not be treated—

''(I) as labeling under the Federal Food, Drug, and Cosmetic Act; or

''(II) as establishing an intended use for purposes of such Act.

''(g) INSPECTIONS.—

''(1) IN GENERAL.—The Secretary may, on an announced or unannounced basis, enter and inspect, during regular hours of operation, laboratories subject to the requirements of this section. In conducting such inspections the Secretary shall have ac-

cess to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection the Secretary may copy any such material or require to it be submitted to the Secretary. An inspection under this paragraph may be made only upon presenting identification to the owner, operator, or agent in charge of the laboratory being inspected.

''(2) COMPLIANCE WITH REQUIREMENTS AND STANDARDS.—The Secretary shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) and the standards issued under subsection (f). Inspections of laboratories not accredited under subsection (e) shall be conducted on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure compliance with such requirements and standards. Inspections of laboratories accredited under subsection (e) shall be conducted on such basis as the Secretary determines is necessary to assure compliance with such requirements and standards.

"(3) SCOPE OF INSPECTIONS.—Any inspections conducted pursuant to this section shall be limited to laboratory operations and related issues and shall not include any inspection related to activities regulated under subchapter J of the Federal Food, Drug, and Cosmetic Act, unless the inspector has been authorized to act on behalf of both the Centers for Medicare & Medicaid Services and the Food and Drug Administration as a hybrid inspector pursuant to paragraph (4).

"(4) HYBRID INSPECTIONS.—

"(A) INTERAGENCY AGREEMENT.—The Commissioner of Food and Drugs may enter into an agreement with the Administrator of the Centers for Medicare & Medicaid Services to jointly train and accredit hybrid inspectors authorized to inspect—

"(i) establishments engaged in the design, development, validation, production, manufacture, preparation, propagation, assembly, or processing of an in vitro clinical test pursuant to subchapter J of the Federal Food, Drug, and Cosmetic Act; and

"(ii) laboratories pursuant to paragraph (1).

"(B) REQUIREMENTS.—A hybrid inspector conducting an inspection pursuant to an agreement under subparagraph (A) shall—

"(i) prior to such inspection, state whether the hybrid inspector intends to conduct an inspection pursuant to subchapter J of the Federal Food, Drug, and Cosmetic Act, paragraph (1), or both;

"(ii) conduct any inspection in accordance with the intent stated under clause (i); and

"(iii) with respect to an establishment that is both engaged in the design, development, validation, production, manufacture, preparation, propagation, assembly, or processing of an in vitro clinical test and operating as a laboratory, if the inspector intends to inspect such establishment pursuant to both subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act and paragraph (1), notify such establishment or laboratory of such intent and maintain a clear distinction between the portions of such inspection conducted pursuant to such subchapter J and

the portions of such inspection conducted pursuant to paragraph (1).

"(C) UNEXPECTED ISSUES.—If during the course of an inspection for which the stated intent is to conduct an inspection pursuant to paragraph (1), a hybrid inspector identifies one or more issues under subchapter J of the Federal Food, Drug, and Cosmetic Act, the hybrid inspector shall—

"(i) notify the establishment or laboratory of the issues and, at the discretion of the inspector, notify the Food and Drug Administration of the issues; and

"(ii) in collaboration with the Food and Drug Administration, determine whether such notice warrants other action under such subchapter J.

"(h) INTERMEDIATE SANCTIONS.—

"(1) IN GENERAL.—If the Secretary determines that a laboratory which has been issued a certificate under this section no longer substantially meets the requirements for the issuance of a certificate, the Secretary may impose intermediate sanctions in lieu of the actions authorized by subsection (i).

''(2) TYPES OF SANCTIONS.—The intermediate sanctions which may be imposed under paragraph (1) shall consist of—

''(A) directed plans of correction;

''(B) civil money penalties in an amount not to exceed $10,000 for each violation listed in subsection (i)(1) or for each day of substantial noncompliance with the requirements;

''(C) payment for the costs of onsite monitoring; or

''(D) any combination of the actions described in subparagraphs (A), (B), and (C).

''(3) PROCEDURES.—The Secretary shall develop and implement procedures with respect to when and how each of the intermediate sanctions is to be imposed under paragraph (1). Such procedures shall provide for notice to the laboratory and a reasonable opportunity to respond to the proposed sanction and appropriate procedures for appealing determinations relating to the imposition of intermediate sanctions.

''(i) SUSPENSION, REVOCATION, AND LIMITATION.—

''(1) IN GENERAL.—Except as provided in paragraph (2), the certificate of a laboratory issued under this section may be suspended, revoked, or

limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory—

"(A) has been guilty of misrepresentation in obtaining the certificate;

"(B) has performed or represented the laboratory as entitled to perform a laboratory examination or other procedure which is not within a category of laboratory examinations or other procedures authorized in the certificate;

"(C) has failed to comply with the requirements of subsection (d) or the standards prescribed by the Secretary under subsection (f);

"(D) has failed to comply with reasonable requests of the Secretary for—

"(i) any information or materials; or

"(ii) work on materials;

that the Secretary concludes is necessary to determine the laboratory's continued eligibility for its certificate or continued compliance with the Secretary's standards under subsection (f);

"(E) has refused a reasonable request of the Secretary, or any Federal officer or employee duly designated by the Secretary, for

permission to inspect the laboratory and its operations and pertinent records during the hours the laboratory is in operation;

"(F) has violated or aided and abetted in the violation of any provisions of this section or of any regulation promulgated thereunder; or

"(G) has not complied with an intermediate sanction imposed under subsection (h).

"(2) ACTION BEFORE A HEARING.—If the Secretary determines that—

"(A) the failure of a laboratory to comply with the standards of the Secretary under subsection (f) presents an imminent and serious risk to human health; or

"(B) a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1);

the Secretary may suspend or limit the certificate of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 60 calendar days from the effective date of the suspension or limitation. A suspension or limitation under this paragraph shall stay in effect until the

decision of the Secretary made after the hearing under paragraph (1).

''(3) INELIGIBILITY TO OWN OR OPERATE LABORATORIES AFTER REVOCATION.—No individual who has owned (other than through a minority interest in publicly traded stock) or directed the daily operations of a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section, except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

''(4) IMPROPER REFERRALS.—

''(A) IN GENERAL.—Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis may have its certificate re-

voked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

"(B) DEFINITION.—In this paragraph, the term 'intentionally refers'—

"(i) means refers with specific intent to circumvent the proficiency testing requirements of this section; and

"(ii) excludes automatic referrals of samples for tests not performed by the referring laboratory in the ordinary course of business.

"(j) INJUNCTIONS.—Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. Upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

"(k) JUDICIAL REVIEW.—

"(1) PETITION.—Any laboratory which has had an intermediate sanction imposed under subsection

(h) or has had its certificate suspended, revoked, or limited under subsection (i) may, at any time within 60 calendar days after the date the action of the Secretary under subsection (i) or (h) becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principal place of business for judicial review of such action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28, United States Code.

''(2) ADDITIONAL EVIDENCE.—If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal of such additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon

such terms and conditions as the court may deem proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file such modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of his original action, with the return of such additional evidence.

''(3) JUDGMENT OF COURT.—Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

''(4) FINALITY OF JUDGMENT.—The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code.

''(l) SANCTIONS.—Any person who intentionally violates any requirement of this section or any regulation

promulgated thereunder shall be imprisoned for not more than one year or fined under title 18, United States Code, or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code, or both.

''(m) FEES.—

''(1) CERTIFICATE FEES.—The Secretary shall require payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver.

''(2) ADDITIONAL FEES.—The Secretary shall require the payment of fees for inspections of laboratories which are not accredited and for the cost of performing proficiency testing on laboratories which do not participate in proficiency testing programs approved under subsection (f)(3)(C).

''(3) CRITERIA.—

''(A) FEES UNDER PARAGRAPH (1).—Fees imposed under paragraph (1) shall be sufficient to cover the general costs of administering this section, including evaluating and monitoring proficiency testing programs approved under subsection (f) and accrediting bodies and imple-

menting and monitoring compliance with the requirements of this section.

''(B) FEES UNDER PARAGRAPH (2).—Fees imposed under paragraph (2) shall be sufficient to cover the cost of the Secretary in carrying out the inspections and proficiency testing described in paragraph (2).

''(C) FEES IMPOSED UNDER PARAGRAPHS (1) AND (2).—Fees imposed under paragraphs (1) and (2) shall vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories.

''(4) CREDIT AGAINST FDA USER FEES.—Any fees paid pursuant to this subsection for the issuance or renewal of a certificate shall be a credit against any user fees due pursuant to **[**_____**]** for the review and approval of an in vitro clinical test. Any such credit is not transferable and may only be used by the facility or affiliated entity actually paying such certification fee and otherwise obligated to pay a user fee pursuant to **[**_____**]**. Such credits must be used in the fiscal year in which such certification fee is paid or the

immediately following fiscal year. Such credits may be applied in the form of a waiver of the user fee otherwise payable, or a waiver of such portion of the otherwise payable user fee as may be covered by the amount of the credit.

''(n) INFORMATION.—On April 1, 1990 and annually thereafter, the Secretary shall compile and make available to physicians and the general public information, based on the previous calendar year, which the Secretary determines is useful in evaluating the performance of a laboratory, including—

''(1) a list of laboratories which have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks,

''(2) a list of laboratories—

''(A) which have had their certificates revoked, suspended, or limited under subsection (i); or

''(B) which have been the subject of a sanction under subsection (l);

together with a statement of the reasons for the revocation, suspension, limitation, or sanction;

''(3) a list of laboratories subject to intermediate sanctions under subsection (h) together with a statement of the reasons for the sanctions;

''(4) a list of laboratories whose accreditation has been withdrawn or revoked together with a statement of the reasons for the withdrawal or revocation;

''(5) a list of laboratories against which the Secretary has taken action under subsection (j) together with a statement of the reasons for such action; and

''(6) a list of laboratories which have been excluded from participation under title XVIII or XIX of the Social Security Act.

The information to be compiled under paragraphs (1) through (6) shall be information for the calendar year preceding the date the information is to be made available to the public and shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraphs.

''(o) DELEGATION.—In carrying out this section, the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or nonprofit private organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as the Secretary may determine.

''(p) STATE LAWS.—

''(1) IN GENERAL.—Except as provided in subparagraph (2), no State, tribal or local government (or political subdivision thereof) may establish or continue in effect with respect to a laboratory, a clinical laboratory, or laboratory operations any requirement which is different from, or in addition to, any requirement applicable under this section to such laboratory, clinical laboratory, or laboratory operations.

''(2) EXCEPTIONS.—Paragraph (1) shall not be construed to affect the authority of a State, tribal, or local government—

''(A) to license health care practitioners or health care facilities or to regulate any aspect of a health care practitioner-patient relationship; or

''(B) to enforce laws of general applicability, such as zoning laws, environmental laws, labor laws, and general business laws.

''(3) CLARIFICATION.—This section shall not be construed to shift liability to health care practitioners.

''(q) CONSULTATIONS.—In carrying out this section, the Secretary shall consult with appropriate private orga-

nizations and public agencies, including the Food and Drug Administration.''.

SEC. 6. TRANSITIONAL PROVISIONS.

(a) CLASSIFICATION.—With respect to an in vitro clinical test that is sought to be first offered after the date of enactment of this Act, but before the effective date of regulations implementing section 590A of the Federal Food, Drug, and Cosmetic Act, as added by section 3 of this Act, the Secretary shall, by regulation—

(1) classify such in vitro clinical test as a low-risk, moderate-risk, or high-risk in vitro clinical test pursuant to such section 590A; and

(2) classify any finished product pursuant to section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c).

(b) QUALITY REQUIREMENTS.—

(1) MANUFACTURERS.—A manufacturer of an in vitro clinical test—

(A) prior to the date of promulgation of final regulations under section 3(e), shall, with respect to such in vitro clinical test, comply with the quality system requirements applicable to devices under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including part 820 of title 21, Code of Federal Regula-

tions, as in effect on the date of enactment of this Act; and

(B) on or after the date of promulgation of final regulations under section 3(e) and before the effective date of such regulations under section 3(e)(2)(A), shall, with respect to such in vitro clinical test, comply with, at the election of the manufacturer—

(i) the quality system requirements described in subparagraph (A); or

(ii) the quality requirements under section 590D of the Federal Food, Drug, and Cosmetic Act, as added by section 3(a).

(2) LABORATORY DEVELOPERS.—A laboratory developer of an in vitro clinical test—

(A) prior to the date of promulgation of final regulations under section 3(e), shall, with respect to such in vitro clinical test, comply with any applicable quality requirements under section 353 of the Public Health and Service Act (42 U.S.C. 263a), as in effect on the day before the date of enactment of this Act; and

(B) on or after the date of promulgation of final regulations under section 3(e) and before

the effective date of such regulations under section 3(e)(2)(A), shall, with respect to such in vitro clinical test, comply with, at the election of the manufacturer—

(i) any applicable quality requirements under section 353 of the Public Health and Service Act (42 U.S.C. 263a), as in effect on the day before the date of enactment of this Act; or

(ii) the quality requirements under section 590D of the Federal Food, Drug, and Cosmetic Act, as added by section 3(a).

(c) SUBMISSION REQUIREMENTS.—

(1) MANUFACTURERS.—A manufacturer of an in vitro clinical test—

(A) with respect to an in vitro clinical test first offered prior to the effective date of final regulations under section 3(e)(2)(B), shall comply with the approval process under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e), the clearance process under section 510(k) of such Act (21 U.S.C. 360(k)), or the listing process under section 510(j) of

such Act (21 U.S.C. 360(j)), as applicable, in effect on the date of enactment of this Act; and

(B) with respect to an in vitro clinical test first in use on or after the effective date of final regulations under section 3(e)(2)(B), shall comply with the premarket submission requirements of sections 590A, 590B, and 590D of the Federal Food, Drug, and Cosmetic Act, as added by section 3(a).

(2) LABORATORIES.—

(A) With respect to an in vitro clinical test first offered on or after the date of enactment of this Act, a laboratory developer of such in vitro clinical test shall—

(i) comply with any applicable premarket requirements pursuant to section 353 of the Public Health and Service Act (42 U.S.C. 263a), as in effect on the day before the date of enactment of this Act; or

(ii) comply with the premarket submission requirements of sections 590A, 590B, and 590D of the Federal Food, Drug, and Cosmetic Act, as added by section 3(a).

(B) If a laboratory developer elects to comply with the premarket requirements specified in subparagraph (A)(i), the laboratory developer shall submit to the Secretary postmarket data establishing a reasonable assurance that the in vitro clinical test is analytically valid and clinically valid. Such data shall be provided not later than 3 years after the promulgation of final regulations under section 3(e) and shall be subject to fees pursuant to **[**section ____**]**.

(C) If a laboratory developer elects to comply with the premarket submission requirements specified in subparagraph (A)(ii), the laboratory developer may immediately offer the in vitro clinical test for use but—

(i) not later than the two years after the promulgation of final regulations under section 3(e), the laboratory developer shall comply with such premarket submission requirements; and

(ii) the corresponding application, notification, or listing for the in vitro clinical test shall not be subject to fees pursuant to **[**section ____**]**.

(d) POSTMARKET REQUIREMENTS.—

(1) MANUFACTURERS.—A manufacturer of an in vitro clinical test—

(A) prior to the date of promulgation of final regulations under section 3(e), shall, with respect to such in vitro clinical test, comply with the postmarket requirements applicable to devices under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including part 803 of title 21, Code of Federal Regulations, as in effect on the date of enactment of this Act; and

(B) on or after the date of promulgation of final regulations under section 3(e) and before the effective date of such regulations under section 3(e)(2)(A), shall, with respect to such in vitro clinical test, comply with, at the election of the manufacturer—

(i) the postmarket requirements applicable to devices under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including part 803 of title 21, Code of Federal Regulations, as in effect on the date of enactment of this Act; or

(ii) the postmarket requirements under section 590E of the Federal Food,

Drug, and Cosmetic Act, as added by section 3(a).

(2) LABORATORY DEVELOPERS.—A laboratory developer of an in vitro clinical test—

(A) prior to the date of promulgation of final regulations under section 3(e), shall, with respect to such in vitro clinical test, comply with any applicable postmarket requirements under section 353 of the Public Health and Service Act (42 U.S.C. 263a), as in effect on the day before the date of enactment of this Act; and

(B) on or after the date of promulgation of final regulations under section 3(e) and before the effective date of such regulations under section 3(e)(2)(A), shall, with respect to such in vitro clinical test, comply with, at the election of the manufacturer—

(i) any applicable postmarket requirements under section 353 of the Public Health and Service Act (42 U.S.C. 263a), as in effect on the day before the date of enactment of this Act; or

(ii) the postmarket requirements under section 590E of the Federal Food,

Drug, and Cosmetic Act, as added by section 3(a).

(e) DEFINITIONS.—In this section:

(1) The term ''developer'' has the meaning given to such term in section 590 of the Federal Food, Drug, and Cosmetic Act, as added by section 3(a).

(2) The term ''device'' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) The term ''finished product'' has the meaning given to such term in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by section 2.

(4) The term ''in vitro clinical test'' has the meaning given to such term in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by section 2.

(5) The term ''laboratory developer'' means a laboratory that is the developer of—

(A) an in vitro clinical test first offered prior to the date of enactment of this Act for which the Secretary did not require an approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e), a clearance

under section 510(k) of such Act (21 U.S.C. 360(k)), or notification under section 510(j) of such Act (21 U.S.C. 360(j)) or otherwise asserted enforcement discretion with regard to such sections and implementing regulations thereunder; or

(B) an in vitro clinical test first offered on or after the date of enactment of this Act for which, prior to such date of enactment, the Secretary would not have required an approval under such section 515, a clearance under such section 510(k), or notification under such section 510(j) or otherwise would have asserted enforcement discretion with regard to such sections and implementing regulations thereunder.

(6) The term ''manufacturer'' means the developer of an in vitro clinical test other than a laboratory developer.