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(Original Signature of Member)

109TH CONGRESS
2D SESSION

H. R. _____

To amend the Public Health Service Act to provide for the licensing of comparable biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. WAXMAN (for himself, [see ATTACHED LIST of cosponsors]) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act to provide for the licensing of comparable biological products, 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.

This Act may be cited as the ''Access to Life-Saving Medicine Act''.

SEC. 2. DEFINITIONS.

Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—

(1) by striking ''In this section, the term 'biological product' means'' and inserting the following: ''In this section:

''(1) The term 'biological product' means''; and

(2) by adding at the end the following:

''(2) The term 'comparable biological product application' means an abbreviated application for a license of a biological product containing the same, or similar, active ingredient as a biological product for which a license has been approved under subsection (a). A comparable biologic application is a human drug application under section 735(1)(C) of the Federal Food, Drug, and Cosmetic Act.

''(3) The term 'reference product' under this Act means the single licensed biological product, approved under subsection (a) or subsection (k), against which a comparable biological product is evaluated for demonstration of safety, potency, or purity.

''(4) The term 'comparable' in reference to a comparable biological product application means the absence of clinically meaningful differences between the comparable biological product and the reference

product in terms of the safety, purity, and potency of the product based upon—

"(A) data derived from chemical, physical, and biological assays, other non-clinical laboratory studies; and

"(B) data from any necessary clinical study or studies sufficient to confirm safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and intended to be used.

Any studies under subparagraph (B) shall be designed to avoid duplicative and unethical clinical testing.

"(5) The term 'thorough characterization' means an analysis of structural features based upon appropriate analytical and functional testing sufficient to identify differences between a new and reference biological product relevant to safety, purity or potency.

"(6) The term 'interchangeable' means that a biological product contains an active ingredient or ingredients with principal molecular structural features comparable to the reference product, and that the comparable biological product can be expected to produce the same clinical result as the reference

product in any given patient in the condition or conditions of use for which both products are labeled.

''(7) The term 'process for the review of a comparable biological product application' means, with respect to a comparable biological product application, the procedural activities of the Secretary with respect to the review of human drug applications and supplements as defined in section 735(6) of the Federal Food, Drug, and Cosmetic Act, except as otherwise defined herein.

''(8) The term 'final action' means, with respect to a comparable biological product application, the Secretary's issuance on the final action date of a final action letter to the sponsor of a comparable biological product application under this Act which—

''(A) approves the application, or

''(B) disapproves the application and sets forth in detail an enumeration of the specific deficiencies in the particular application and of the specific, enumerated actions the sponsor would be required to take in order for the sponsor to receive a final action letter that approves such application.

''(9) The term 'final action date' means, with respect to an abbreviated comparable biological

product application, the date that is eight calendar months following the sponsor's submission of such application, or 180 days following the Secretary's notification of the sponsor that its application has been accepted for filing, whichever is earlier, except that the final action date hereunder may be extended for such period of time as is agreed to by the Secretary and the sponsor of such application in a jointly executed written agreement that is countersigned by the Secretary and the sponsor of such application no later than 30 days prior to the final action date provided for by this subsection.

''(10) The term 'reviewing division' means the division responsible for the review of an application for approval of a biological product (including all scientific and medical matters, chemistry, manufacturing, and controls).''.

SEC. 3. REGULATION OF CERTAIN BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting after ''biologics license'' the following: '', or comparable biologics license,''; and

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

''(k) REGULATION OF COMPARABLE BIOLOGICAL PRODUCTS.—

''(1) SUBMISSION OF A COMPARABLE BIOLOGICAL PRODUCT APPLICATION.—Any person may file with the Secretary an abbreviated comparable biological product application that includes the following:

''(A) Data demonstrating that the comparable biological product is comparable to the reference product.

''(B) Data demonstrating that the comparable biological product and reference product contain comparable principal molecular structural features as demonstrated by thorough characterization of the two products, notwithstanding minor differences in heterogeneity profile, impurities, or degradation patterns. The Secretary shall find the following types of products to contain comparable principal molecular structural features:

''(i) Two protein biological products with differences in structure between them solely due to post-translational events, infidelity of translation or transcription, or minor differences in amino acid sequence.

''(ii) Two polysaccharide biological products with similar saccharide repeating units, even if the number of units differ and even if there are differences in post-polymerization modifications.

''(iii) Two glycosylated protein products with differences in structure between them solely due to post-translational events, infidelity of translation or transcription, or minor differences in amino acid sequence, and if they had similar saccharide repeating units, even if the number of units differ and even if there were differences in post-polymerization.

''(iv) Two polynucleotide biological products with identical sequence of purine and pyrimidine bases (or their derivatives) bound to an identical sugar backbone (ribose, deoxyribose, or modifications of these sugars).

''(v) Closely related, complex partly definable biological products with similar therapeutic intent, such as two live viral products for the same indication.

The principal molecular structural features of two biological products not enumerated in the foregoing clauses may be demonstrated to be comparable based upon such data and other information characterizing the two products as the Secretary determines to be necessary.

''(C) Data demonstrating that the comparable biological product and reference product utilize the same mechanism or mechanisms of action for the conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product.

''(D) Information to show that the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the comparable biological product have been previously approved for the reference product.

''(E) Information to show that the route of administration, the dosage form, and the strength of the comparable biological product are the same as those of the reference product.

''(F) Data demonstrating that the facility in which the comparable biological product is manufactured, processed, packed, or held meets standards designed to assure that the comparable biological product continues to be safe, pure, and potent.

''(G) At the applicant's option, publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent.

''(H) Any additional data and information in support of the application, including publicly-available information with respect to the reference product or another biological product.

''(2) OTHER APPLICATIONS.—A person who has not conducted and does not have a right of reference to the studies in the application for a reference product may submit an application under this section for a biologic product that differs from, or incorporates a change to, the reference product with respect to one or more characteristics described in subparagraphs (A) through (E) of paragraph (1), including a difference in safety, purity, or potency, so long as the application contains sufficient information to establish the safety, purity, and potency of the biologi-

cal product relative to the reference product for its proposed condition or conditions of use.

''(3) POSTMARKETING STUDIES.—If the Secretary has agreed with the sponsor of the reference product that the sponsor shall conduct one or more postmarketing safety studies, the applicant may agree with the Secretary to conduct a similar postmarketing safety study or studies upon a reasonable showing that such study or studies would provide relevant information not available from the studies on the reference product. The Secretary shall not, as a condition of approval, propose any additional postmarketing studies.

''(4) FDA REVIEW OF COMPARABLE BIOLOGICAL PRODUCT APPLICATIONS.—

''(A) GUIDANCE REGARDING REVIEW OF APPLICATIONS.—The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or (2), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

''(B) MEETINGS WITH SPONSORS AND APPLICANTS.—The Secretary shall meet with a sponsor of an investigation or an applicant for approval of a comparable biological product under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

''(C) AGREEMENTS.—Any agreement regarding the parameters of design and size of the studies of a biological product under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

''(i) with the written agreement of the sponsor or applicant; or

"(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety, purity, and potency of the biological product has been identified after the testing has begun.

"(D) PROCEDURE REGARDING CERTAIN DECISIONS.—A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

"(E) EFFECT OF DECISIONS.—The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

"(F) DELAYS BY REVIEWING DIVISIONS.—No action by the reviewing division may be delayed because of the unavailability of informa-

tion from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe, pure, and potent biological product.

''(5) APPROVAL OF COMPARABLE BIOLOGICAL PRODUCTS.—The Secretary shall review the information submitted in the application and any other information available to the Secretary and shall issue, subject to paragraph (9), a comparable biological product license for all conditions of use of the reference product sharing the same mechanism of action for which the applicant has demonstrated comparability for a single condition of use, or, if the mechanism of action is unknown, for the condition or conditions of use for which the data submitted establishes comparability, unless the Secretary finds and informs the applicant that—

''(A) information submitted in the application or any other information available to the Secretary is insufficient to show that the comparable biological product and the reference product contain comparable principal molecular structural features as demonstrated by thorough characterization of the two products;

"(B) information submitted in the application or any other information available to the Secretary is insufficient to show that the comparable biological product is comparable to the reference product for the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed in the application;

"(C) information submitted in the application or any other information available to the Secretary is insufficient to show that the comparable biological product and reference product utilize the same mechanism or mechanisms of action for the conditions of use prescribed, recommended, or suggested in the labeling proposed for the comparable biological product, unless the mechanism or mechanisms of action are not known for the reference product for such condition or conditions;

"(D) information submitted in the application or any other information available to the Secretary is insufficient to show that the route of administration, the dosage form, and the strength of the comparable biological product are the same as those of the reference product;

"(E) information submitted in the application or any other information available to the Secretary is insufficient to show that the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the comparable biological product are limited to one or more of the same use or uses as have been previously approved for the reference product;

"(F) information submitted in the application or any other information available to the Secretary shows (i) the inactive ingredients of the comparable biological product are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the biological product, or (ii) the composition of the comparable biological product is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

"(G) information submitted in the application or any other information available to the Secretary fails to demonstrate that the facility in which the comparable biological product is

manufactured, processed, packed, or held meets standards designed to assure that the comparable biological product continues to be safe, pure, and potent;

''(H) the Secretary has withdrawn or suspended the license of the reference product, for safety or effectiveness reasons, or has published a notice of opportunity for hearing to withdraw such license for safety or effectiveness reasons, or the Secretary has determined that the reference product has been withdrawn from sale for safety or effectiveness reasons; or

''(I) the application contains an untrue statement of material fact; and

provides the applicant with a detailed explanation for the decision.

''(6) OTHER APPROVAL PROVISIONS.—The Secretary shall approve, under the provisions of paragraph (5), an application for a license submitted under paragraph (2), except that the Secretary shall approve such an application that would otherwise be disapproved by reason of one or more of subparagraphs (A) through (E) of paragraph (5), if the application and any other information available to the Secretary contains sufficient information to establish

the safety, purity, and potency of the comparable biological product relative to the reference product for the proposed condition or conditions of use for such product.

''(7) INTERCHANGEABILITY DETERMINATIONS FOR COMPARABLE BIOLOGICAL PRODUCTS.—An applicant may request in an original application or supplement to an application that the Secretary make a determination as to the interchangeability of a comparable biological product and the reference product. An applicant may withdraw a request for a determination at any time. A request for an interchangeability determination submitted after the filing of an application shall be considered a major amendment to the application. In response to such a request, the Secretary shall, at such time as the application or supplement is approved, publish a therapeutic comparability evaluation code indicating either that the comparable biological product has been shown to be interchangeable with the reference product, or that interchangeability has not been established. Nothing in this subsection shall be construed to prohibit the Secretary from making a determination of interchangeability at any time after approval.

''(8) INTERCHANGEABILITY LABELING FOR COMPARABLE BIOLOGICAL PRODUCTS.—Upon a determination of interchangeability under paragraph (7), the label of the comparable biological product at the time of licensure may include a statement, if requested by the sponsor, that it is interchangeable with the biological reference product to which the sponsor of the comparable biological product application has demonstrated comparability to the reference product for the conditions of use prescribed, recommended, or suggested in the labeling proposed for the comparable biological product.

''(9) EXCLUSIVITY.—

''(A) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall not approve a second or subsequent comparable biological product application, and no holder of a biologic product license approved under subsection (a) shall manufacture, market, sell, or distribute a rebranded interchangeable biologic, directly or indirectly, or authorize any other person to manufacture, market, sell, or distribute a rebranded interchangeable biologic that is interchangeable with the reference product, until the earlier of—

"(i) 180 days after the first commercial marketing of the first interchangeable comparable biological product to be approved as interchangeable for that same reference product;

"(ii) one year after—

"(I) a final court decision on all patents in suit in an action instituted under paragraph (16)(C) against the applicant that submitted the application for the first approved interchangeable comparable biological product; or

"(II) the dismissal with or without prejudice of an action instituted under paragraph (16)(C) against the applicant that submitted the application for the first approved interchangeable comparable biological product; or

"(iii)(I) 36 months after approval of the first interchangeable comparable biological product if the applicant has been sued under paragraph (16)(C) and such

litigation is still ongoing within such 36-month period; or

"(II) one year after approval in the event that the first approved interchangeable comparable applicant has not been sued under paragraph (16)(C).

Notwithstanding the foregoing provision, the sponsor of a subsequent comparable biological product application that has demonstrated interchangeability with the reference product may elect, at its option, to have the product approved as a non-interchangeable comparable biological product whose approval will not be delayed by operation of this paragraph. For purposes of this paragraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

"(B) REBRANDED INTERCHANGEABLE BIOLOGIC.—For purposes of this subsection, the term 'rebranded interchangeable biologic'—

"(i) means any rebranded interchangeable version of a reference product that the holder of the biological product li-

cense approved under subsection (a) for that reference product seeks to commence marketing, selling, or distributing, directly or indirectly; and

"(ii) does not include any product to be marketed, sold, or distributed—

"(I) by an entity eligible for exclusivity with respect to such product under this paragraph; or

"(II) after expiration of any exclusivity with respect to such product under this paragraph.

"(10) HEARING.—If the Secretary decides to disapprove a comparable biological product application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety

days after the date fixed by the Secretary for filing final briefs.

''(11) FINAL ACTION DATE.—The Secretary shall take a final action on a comparable biological product application by the final action date.

''(12) REQUEST FOR DELAY OF FINAL ACTION.—Notwithstanding any other provision of law, the Secretary shall not fail or refuse to take a final action on a comparable biological product application by the final action date on the basis that a person, other than the sponsor of the comparable biological product, has requested (in a petition or otherwise) that the Secretary refuse to take or otherwise defer such final action, and no court shall enjoin the Secretary from taking final action or stay the effect of final action previously taken by the Secretary, except by issuance of a permanent injunction based upon an express finding of clear and convincing evidence that the person seeking to have the Secretary refuse to take or otherwise to deter final action by the final action date—

''(A) has prevailed on the merits of the person's complaint against the Secretary;

''(B) will suffer imminent and actual irreparable injury, constituting more than irrecover-

able economic loss, and that also will threaten imminent destruction of such person's business; and

"(C) has an interest that outweighs the overwhelming interest that the public has in obtaining prompt access to a comparable biological product.

"(13) REPORT ON EXTENSIONS OF FINAL ACTION DATE.—The Secretary shall prepare and submit to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding any jointly executed written agreement to extend the final action date under this Act within 15 calendar days of the joint execution of any such written agreement.

"(14) REPORT ON FAILURE TO TAKE FINAL ACTION.—The Secretary shall prepare and submit annually to the President, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate a report detailing the specific and particularized reasons enumerated by the Reviewing Division for each instance of the Secretary's

failure to take final action by the final action date in the previous year.

''(15) REGULATIONS.—The Secretary shall establish, by regulation within 2 years after the date of the enactment of this subsection, requirements for the efficient review, approval, suspension, and revocation of comparable biological product applications under this subsection.

''(16) PATENTS.—

''(A) REQUEST FOR PATENT INFORMATION.—

''(i) IN GENERAL.—At any time, including at the initial stages of development, an applicant or a prospective applicant may send a written request for patent information to the holder of the approved application for the reference product. Within 60 days of receipt of such request, the holder of the approved application for the reference product shall provide to the applicant or prospective applicant a list of all patents owned by, or licensed to, the holder of the approved application that the application holder in good faith believes relate to the reference product, including

patents that claim the approved biologic product, any method of using such product, any component of such product, or any method or process of manufacturing such product or component.

''(ii) COSTS OF COMPLYING WITH REQUEST.—The application holder may demand payment not exceeding $1,000 to offset the cost of responding to the information request.

''(iii) UPDATES.—For a period of two years from the date of the request for information, the holder of the approved application for the reference product shall update its response to the request for information by identifying newly issued or licensed relevant patents. The updates must be provided within 30 days of patent issuance, for newly issued patents, and within 30 days of obtaining a license, for newly licensed patents.

''(iv) ADDITIONAL REQUESTS.—The applicant may submit additional requests for patent information, subject to the requirements of this paragraph, at any time.

"(B) PATENT NOTIFICATIONS.—At any time after the submission of the application, the applicant may provide a notice under this subparagraph with respect to any one or more patents provided by the holder of the reference product provided in response to a request under this paragraph. An applicant may submit additional notices at any time, and each notice shall be subject to the provisions of this subparagraph. Each notice shall—

"(i) be sent to the holder of approved application for the reference product and to the owner of the patent identified pursuant to subparagraph (A)(i);

"(ii) include a detailed statement of the factual and legal bases for the applicant's belief that the patents included in the notice are invalid, unenforceable, or will not be infringed by the commercial sale of the product for which approval is or has been sought; and

"(iii) identify the judicial district or districts in which the applicant consents to suit being brought in response to the notice.

"(C) ACTION FOR INFRINGEMENT.—

"(i) TIMEFRAME FOR BRINGING ACTION.—Within 45 days of receipt of notice described in subparagraph (B), the holder of the approved application for the reference product, or the owner of the patent, may bring an action infringement solely with respect to the patent or patents included in such notice.

"(ii) APPROPRIATE JUDICIAL DISTRICT.—Notwithstanding section 1391 of title 28, United States Code, an infringement action brought within the 45-day period referenced in clause (i) may be brought only in the judicial district identified pursuant to subparagraph (B)(iii).

"(D) LIMITATION ON DECLARATORY JUDGMENT ACTIONS.—No action may be brought under section 2201 of title 28, United States Code by the recipient of a notice under subparagraph (B) for a declaration of infringement, validity, or enforceability with respect to any patent which was not identified in the notice, and with respect to the application under which the notice was sent, or with respect to

the product of that application, prior to the commercial marketing of that product. With respect to a patent identified in the notice, notwithstanding section 1391 of title 28, any such action may be brought only in the judicial districts identified in the notice.

''(E) DISCRETION OF APPLICANTS.—A comparable biological product applicant may not be compelled, by court order or otherwise, to initiate the procedures set forth in this paragraph. The decision as to whether to invoke the procedures set forth in this paragraph is left entirely to the discretion of the applicant or prospective applicant.

''(17) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

''(A) IN GENERAL.—With respect to a pending application submitted under paragraph (1) or (2), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, the following applies, subject to subparagraph (E):

''(i) (I) In the case of an application under paragraph (2), the Secretary may not, subject to subclause (III), consider the petition if it is submitted later than 180 days prior to the date on which the approval of the application may first be made effective.

''(II) In the case of an application under paragraph (1), the Secretary may not, subject to subclause (III), consider the petition if it is submitted later than 180 days prior to the date on which the approval of the application may first be made effective.

''(III) The restriction established in subclause (I) or (II) (as the case may be) does not apply to the petition if the Secretary determines that the petitioner has shown good cause for the failure to submit the petition by the applicable date under such subclause.

''(ii)(I) The Secretary may not, on the basis of the petition, delay approval of the application unless the Secretary determines that a delay is necessary to protect the

public health. Consideration of a petition shall be separate and apart from the review and approval of the application.

"(II) With respect to a determination by the Secretary under subclause (I) that a delay is necessary to protect the public health:

"(aa) The Secretary shall publish on the Internet site of the Food and Drug Administration a statement providing the reasons underlying the determination.

"(bb) Not later than 10 days after making the determination, the Secretary shall provide notice to the sponsor of the application and an opportunity for a meeting with the Commissioner to discuss the determination.

"(iii) The Secretary shall take final agency action on the petition not later than 180 days after the date on which the petition is submitted. The Secretary shall not extend such period, even with the consent of the petitioner, for any reason, in-

cluding based upon the submission of comments relating to the petition or supplemental information supplied by the petitioner.

''(iv) The Secretary may not consider the petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. I received or expect to receive payments, including cash and other forms of consideration, from the following

persons or organizations to file this petition: _____. I verify under penalty of perjury that the foregoing is true and correct.'.

''(B) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

''(i) FINAL AGENCY ACTION WITHIN 180 DAYS.—The Secretary shall be considered to have taken final agency action on a petition referred to in subparagraph (A) if—

''(I) during the 180-day period referred to in clause (iii) of such subparagraph, the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations; or

''(II) such period expires without the Secretary having made such a final decision.

''(ii) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed with respect to a petition referred to in subparagraph (A) before final agency action within the meaning of clause (i) has occurred, the

court shall dismiss the action for failure to exhaust administrative remedies.

''(C) APPLICABILITY OF CERTAIN REGULATIONS.—The provisions of this section are in addition to the requirements for the submission of a petition to the Secretary that apply under section 10.30 or 10.35 of title 21, Code of Federal Regulations.

''(D) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

''(i) the number of applications under this subsection that were approved during the preceding 12-month period;

''(ii) the number of such applications whose effective dates were delayed by petitions referred to in subparagraph (A) during such period; and

''(iii) the number of days by which the applications were so delayed.

''(E) EXCEPTION.—This paragraph does not apply to a petition that is made by the sponsor of an application under this subsection and that seeks only to have the Secretary take

or refrain from taking any form of action with respect to that application.

''(F) DEFINITION.—For purposes of this paragraph, the term 'petition' includes any request to the Secretary, without regard to whether the request is characterized as a petition.''.

(b) ADDITIONAL AMENDMENTS.—

(1) PATENTS.—Section 271(e) of title 35, United States Code, is amended—

(A) in paragraph (2)—

(i) by striking ''or'' at the end of subparagraph (A);

(ii) by adding ''or'' at the end of subparagraph (B);

(iii) by inserting after subparagraph (B) the following:

''(C) a notice described in section 351(k)(16)(B) of the Public Health Service Act, but only with respect to a patent identified in such a notice,''; and

(iv) in the matter after and below subparagraph (C) (as inserted by clause (iii) of this subparagraph), by inserting before the period the following: '', or if the notice

described in subparagraph (C) is provided in connection with an application to obtain a license to engage in the commercial manufacture, use, or sale of a biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent'' ; and

(B) by adding at the end the following paragraph:

''(5) Notwithstanding the preceding subsection:

''(A) A patent that is disclosed in a response to a request for patent information pursuant to subparagraph (A) of section 351(k)(16) of the Public Health Service Act with respect to which a notice was provided pursuant to subparagraph (B) of such section, and for which an action for infringement of the patent was (I) brought after the expiration of the 45-day period described in such subparagraph, or (II) brought before the expiration of the 45-day period described in such section 351, but not maintained through a final court decision or a dismissal with prejudice regarding the validity, enforceability, and/or infringement, the sole and exclusive remedy which may be granted by a court upon a finding of infringement of such patent by the person who sub-

mitted the notice described in subclause (A), or any person found to have induced or contributed to such infringement, shall be a reasonable royalty.

''(B) No action for infringement can be brought under this section against an applicant that sent a request for patent information pursuant to subparagraph (A)(i) of section 351(k)(16) of the Public Health Service Act by the owner of a patent that should have been disclosed in response to such a request, but was not timely disclosed under that subparagraph.' ''.

(2) TAX CREDIT TESTING TO DEMONSTRATE INTERCHANGEABLITY.—Subpart A of part IV of subchapter A of chapter 1 of the Internal Revenue Code of 1954 (relating to credits allowable) is amended by inserting after section 45C the following new section:

''SEC. 45C-1. CLINICAL TESTING EXPENSES FOR CERTAIN DRUGS TO DEMONSTRATE INTERCHANGEABILITY.

''(a) GENERAL RULE.—There shall be allowed as a credit against the tax imposed by this chapter for the taxable year an amount equal to 50 percent of the qualified clinical testing expenses for the taxable year.

''(b) QUALIFIED CLINICAL TESTING EXPENSES.—For purposes of this section—

''(1) QUALIFIED CLINICAL TESTING EXPENSES.—

''(A) IN GENERAL.—Except as otherwise provided in this paragraph, the term 'qualified clinical testing expenses' means the amounts which are paid or incurred by the taxpayer during the taxable year which would be described in subsection (b) of section 41 if such subsection were applied with the modifications set forth in subparagraph (B).

''(B) MODIFICATIONS.—For purposes of subparagraph (A), subsection (b) of section 41 shall be applied—

''(i) by substituting 'clinical testing' for 'qualified research' each place it appears in paragraphs (2) and (3) of such subsection, and

''(ii) by substituting '100 percent' for '65 percent' in paragraph (3)(A) of such subsection.

''(D) SPECIAL RULE.—For purposes of this paragraph, section 41 shall be deemed to

remain in effect for periods after December 31, 2006.

''(2) CLINICAL TESTING.—The term 'clinical testing' means any human clinical testing which is carried out under an exemption for a drug being tested for interchangeability under section 351(k) of the Public Health Service Act.

''(3) SPECIAL LIMITATIONS ON FOREIGN TESTING.—

''(A) IN GENERAL.—No credit shall be allowed under this section with respect to any clinical testing conducted outside the United States unless—

''(i) such testing is conducted outside the United States because there is an insufficient testing population in the United States, and

''(ii) such testing is conducted by a United States person or by any other person who is not related to the taxpayer seeking the interchangeable designation under section 351(k) of the Public Health Service Act.

''(B) SPECIAL LIMITATION FOR CORPORATIONS TO WHICH SECTION 936 APPLIES.—No

credit shall be allowed under this section with respect to any clinical testing conducted by a corporation to which section 934(b) applies or to which an election under section 936 applies.

''(4) CERTAIN RULES MADE APPLICABLE.—Rules similar to the rules of paragraphs (1) and (2) of section 41(f) shall apply for purposes of this section.

''(5) ELECTION.—This section shall apply to any taxpayer for any taxable year only if such taxpayer elects (at such time and in such manner as the Secretary may by regulations prescribe) to have this section apply for such taxable year.''.

(3) CONFORMING AMENDMENT.—Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: '', or section 351 of the Public Health Service Act''.