

110TH CONGRESS  
1ST SESSION

# H. R. 1038

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

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## IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 14, 2007

Mr. WAXMAN (for himself, Mrs. EMERSON, Mr. PALLONE, Mr. EMANUEL, and Ms. HIRONO) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

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

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Access to Life-Saving  
5 Medicine Act”.

6 **SEC. 2. DEFINITIONS.**

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

1           (1) by striking “In this section, the term ‘bio-  
2           logical product’ means” and inserting the following:

3           “In this section:

4           “(1) The term ‘biological product’ means”; and

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

6           “(2) The term ‘abbreviated biological product  
7           application’ means an abbreviated application for a  
8           license of a biological product containing the same,  
9           or similar, active ingredient as a reference product.

10          “(3) The term ‘reference product’ means the  
11          single licensed biological product, approved under  
12          subsection (a) or subsection (k), against which a bio-  
13          logical product is evaluated for demonstration of  
14          safety, potency, or purity.

15          “(4) The term ‘comparable’ or ‘comparability’  
16          in reference to a biological product means the ab-  
17          sence of clinically meaningful differences between  
18          the biological product and the reference product in  
19          terms of the safety, purity, and potency of the prod-  
20          uct based upon—

21                 “(A) data derived from chemical, physical,  
22                 and biological assays, and other non-clinical  
23                 laboratory studies; and

24                 “(B) data from any necessary clinical  
25                 study or studies sufficient to confirm safety,

1           purity, and potency in one or more appropriate  
2           conditions of use for which the reference prod-  
3           uct is licensed and intended to be used.

4           Any studies under subparagraph (B) shall be de-  
5           signed to avoid duplicative and unethical clinical  
6           testing.

7           “(5) The terms ‘interchangeable’ and ‘inter-  
8           changeability’ mean, with respect to the condition of  
9           use involved, that the biological product—

10                   “(A) is comparable to the reference prod-  
11                   uct; and

12                   “(B) can be expected to produce the same  
13                   clinical result as the reference product in any  
14                   given patient.

15           “(6) The term ‘thorough characterization’  
16           means an analysis of structural features based upon  
17           appropriate analytical and functional testing suffi-  
18           cient to identify differences between a biological  
19           product and reference product relevant to safety, pu-  
20           rity or potency.

21           “(7) The term ‘final action’ means, with respect  
22           to an abbreviated biological product application, the  
23           Secretary’s issuance of a final action letter to the  
24           sponsor of an abbreviated biological product applica-  
25           tion which—

1                   “(A) approves the application; or

2                   “(B) disapproves the application and sets  
3                   forth in detail an enumeration of the specific  
4                   deficiencies in the particular application and of  
5                   the specific, enumerated actions the sponsor  
6                   would be required to take in order for the spon-  
7                   sor to receive a final action letter that approves  
8                   such application.

9                   “(8) The term ‘final action date’ means, with  
10                  respect to an abbreviated biological product applica-  
11                  tion, the date by which the Secretary must take a  
12                  final action on the application pursuant to sub-  
13                  section (k)(11).

14                  “(9) The term ‘reviewing division’ means the  
15                  division responsible for the review of an application  
16                  for approval of a biological product (including all sci-  
17                  entific and medical matters, chemistry, manufac-  
18                  turing, and controls).”.

19                  (b) RULE OF CONSTRUCTION.—Nothing in this Act  
20                  or the amendments made by this Act shall be construed  
21                  to exclude an application for licensure of a biological prod-  
22                  uct under section 351(k) from the definition of a human  
23                  drug application in section 735(1)(C) of the Federal Food,  
24                  Drug, and Cosmetic Act (21 U.S.C. 379g(1)(C)).

1 **SEC. 3. REGULATION OF COMPARABLE AND INTERCHANGE-**  
2 **ABLE BIOLOGICAL PRODUCTS.**

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

5 (1) in subsection (a)(1)(A), by inserting “under  
6 this subsection or subsection (k)” after “biologics li-  
7 cense”; and

8 (2) by adding at the end the following sub-  
9 section:

10 “(k) REGULATION OF COMPARABLE AND INTER-  
11 CHANGEABLE BIOLOGICAL PRODUCTS.—

12 “(1) SUBMISSION OF AN ABBREVIATED BIO-  
13 LOGICAL PRODUCT APPLICATION.—Any person may  
14 file with the Secretary an abbreviated biological  
15 product application. Any such application shall in-  
16 clude the following:

17 “(A) Data demonstrating that the biologi-  
18 cal product is comparable to or interchangeable  
19 with the reference product.

20 “(B) Data demonstrating that the biologi-  
21 cal product and reference product contain high-  
22 ly similar principal molecular structural fea-  
23 tures, notwithstanding minor differences in het-  
24 erogeneity profile, impurities, or degradation  
25 patterns. The Secretary shall find the following

1 types of products to contain highly similar prin-  
2 cipal molecular structural features:

3 “(i) Two protein biological products  
4 with differences in structure between them  
5 solely due to post-translational events, infi-  
6 delity of translation or transcription, or  
7 minor differences in amino acid sequence.

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

13 “(iii) Two glycosylated protein prod-  
14 ucts with differences in structure between  
15 them solely due to post-translational  
16 events, infidelity of translation or tran-  
17 scription, or minor differences in amino  
18 acid sequence, and if they had similar sac-  
19 charide repeating units, even if the number  
20 of units differ and even if there were dif-  
21 ferences in post-polymerization modifica-  
22 tions.

23 “(iv) Two polynucleotide biological  
24 products with identical sequence of purine  
25 and pyrimidine bases (or their derivatives)

1 bound to an identical sugar backbone (ri-  
2 bose, deoxyribose, or modifications of these  
3 sugars).

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

8 Two biological products not enumerated in the  
9 foregoing clauses may be demonstrated to con-  
10 tain highly similar principal molecular struc-  
11 tural features based upon such data and other  
12 information characterizing the two products as  
13 the Secretary determines to be necessary.

14 “(C) Data demonstrating that the biologi-  
15 cal product and reference product utilize the  
16 same mechanism or mechanisms of action for  
17 the condition or conditions of use prescribed,  
18 recommended, or suggested in the proposed la-  
19 beling, but only to the extent the mechanism or  
20 mechanisms of action are known for the ref-  
21 erence product.

22 “(D) Information to show that the condi-  
23 tion or conditions of use prescribed, rec-  
24 ommended, or suggested in the labeling pro-

1           posed for the biological product have been pre-  
2           viously approved for the reference product.

3           “(E) Information to show that the route of  
4           administration, the dosage form, and the  
5           strength of the biological product are the same  
6           as those of the reference product.

7           “(F) Data demonstrating that the facility  
8           in which the biological product is manufactured,  
9           processed, packed, or held meets standards de-  
10          signed to assure that the biological product con-  
11          tinues to be safe, pure, and potent.

12          “(G) At the applicant’s option, publicly-  
13          available information regarding the Secretary’s  
14          previous determination that the reference prod-  
15          uct is safe, pure, and potent.

16          “(H) Any additional data and information  
17          in support of the application, including publicly-  
18          available information with respect to the ref-  
19          erence product or another biological product.

20          “(2) OTHER APPLICATIONS.—Any person, in-  
21          cluding a person who has not conducted and does  
22          not have a right of reference to the studies in the  
23          application for a reference product, may submit an  
24          application under this paragraph for a biological  
25          product that differs from, or incorporates a change

1 to, the reference product with respect to one or more  
2 characteristics described in subparagraphs (A)  
3 through (E) of paragraph (1), including a difference  
4 in safety, purity, or potency, so long as the applica-  
5 tion contains sufficient information to establish the  
6 safety, purity, and potency of the biological product  
7 relative to the reference product for its proposed  
8 condition or conditions of use.

9 “(3) FDA REVIEW OF ABBREVIATED BIOLOGI-  
10 CAL PRODUCT APPLICATIONS.—

11 “(A) GUIDANCE REGARDING REVIEW OF  
12 APPLICATIONS.—The Secretary shall issue guid-  
13 ance for the individuals who review applications  
14 submitted under paragraph (1) or (2), which  
15 shall relate to promptness in conducting the re-  
16 view, technical excellence, lack of bias and con-  
17 flict of interest, and knowledge of regulatory  
18 and scientific standards, and which shall apply  
19 equally to all individuals who review such appli-  
20 cations.

21 “(B) MEETINGS WITH SPONSORS AND AP-  
22 PPLICANTS.—The Secretary shall meet with a  
23 sponsor of an investigation or an applicant for  
24 approval of a comparable or interchangeable bi-  
25 ological product under this subsection if the

1 sponsor or applicant makes a reasonable writ-  
2 ten request for a meeting for the purpose of  
3 reaching agreement on the design and size of  
4 studies needed for approval of the application.  
5 The sponsor or applicant shall provide informa-  
6 tion necessary for discussion and agreement on  
7 the design and size of such studies. Minutes of  
8 any such meeting shall be prepared by the Sec-  
9 retary and made available to the sponsor or ap-  
10 plicant.

11 “(C) AGREEMENTS.—Any agreement re-  
12 garding the parameters of design and size of  
13 the studies of a biological product under this  
14 paragraph that is reached between the Sec-  
15 retary and a sponsor or applicant shall be re-  
16 duced to writing and made part of the adminis-  
17 trative record by the Secretary. Such agreement  
18 shall not be changed after the testing begins,  
19 except—

20 “(i) with the written agreement of the  
21 sponsor or applicant; or

22 “(ii) pursuant to a decision, made in  
23 accordance with subparagraph (D) by the  
24 director of the reviewing division, that a  
25 substantial scientific issue essential to de-

1           termining the safety, purity, and potency  
2           of the biological product has been identi-  
3           fied after the testing has begun.

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

12          “(E) EFFECT OF DECISIONS.—The written  
13          decisions of the reviewing division shall be bind-  
14          ing upon, and may not directly or indirectly be  
15          changed by, the field or compliance office per-  
16          sonnel unless such field or compliance office  
17          personnel demonstrate to the reviewing division  
18          why such decision should be modified.

19          “(F) DELAYS BY REVIEWING DIVISIONS.—  
20          No action by the reviewing division may be de-  
21          layed because of the unavailability of informa-  
22          tion from or action by field personnel unless the  
23          reviewing division determines that a delay is  
24          necessary to assure the marketing of a safe,  
25          pure, and potent biological product.

1           “(4) APPROVAL OF COMPARABLE OR INTER-  
2 CHANGEABLE BIOLOGICAL PRODUCTS.—

3           “(A) DETERMINATION OF COM-  
4 PARABILITY.—Upon review of an application  
5 submitted under paragraph (1) or (2) for a bio-  
6 logical product, the Secretary shall issue a com-  
7 parable biological product license for all condi-  
8 tions of use of the reference product sharing  
9 the same mechanism or mechanisms of action  
10 for which the applicant has demonstrated com-  
11 parability for a single condition of use, or, if the  
12 mechanism or mechanisms of action are un-  
13 known, for the condition or conditions of use  
14 for which the data submitted establishes com-  
15 parability, unless the Secretary finds and in-  
16 forms the applicant that—

17           “(i) information submitted in the ap-  
18 plication or any other information available  
19 to the Secretary is insufficient to show  
20 that the biological product is comparable  
21 to the reference product for the condition  
22 or conditions of use prescribed, rec-  
23 ommended, or suggested in the labeling  
24 proposed in the application;

1           “(ii) information submitted in the ap-  
2           plication or any other information available  
3           to the Secretary is insufficient to show  
4           that the biological product and the ref-  
5           erence product contain highly similar prin-  
6           cipal molecular structural features, not-  
7           withstanding minor differences in hetero-  
8           geneity profile, impurities, or degradation  
9           patterns;

10           “(iii) information submitted in the ap-  
11           plication or any other information available  
12           to the Secretary is insufficient to show  
13           that the biological product and reference  
14           product utilize the same mechanism or  
15           mechanisms of action for the conditions of  
16           use prescribed, recommended, or suggested  
17           in the labeling proposed for the biological  
18           product, unless the mechanism or mecha-  
19           nisms of action are not known for the ref-  
20           erence product for such condition or condi-  
21           tions;

22           “(iv) information submitted in the ap-  
23           plication or any other information available  
24           to the Secretary is insufficient to show  
25           that the route of administration, the dos-

1 age form, and the strength of the biological  
2 product are the same as those of the ref-  
3 erence product;

4 “(v) information submitted in the ap-  
5 plication or any other information available  
6 to the Secretary is insufficient to show  
7 that the condition or conditions of use pre-  
8 scribed, recommended, or suggested in the  
9 labeling proposed for the biological product  
10 are limited to one or more of the same use  
11 or uses as have been previously approved  
12 for the reference product;

13 “(vi) information submitted in the ap-  
14 plication or any other information available  
15 to the Secretary shows (I) the inactive in-  
16 gredients of the biological product are un-  
17 safe for use under the conditions pre-  
18 scribed, recommended, or suggested in the  
19 labeling proposed for the biological prod-  
20 uct, or (II) the composition of the biologi-  
21 cal product is unsafe under such conditions  
22 because of the type or quantity of inactive  
23 ingredients included or the manner in  
24 which the inactive ingredients are included;

1           “(vii) information submitted in the  
2           application or any other information avail-  
3           able to the Secretary fails to demonstrate  
4           that the facility in which the biological  
5           product is manufactured, processed,  
6           packed, or held meets standards designed  
7           to assure that the biological product con-  
8           tinues to be safe, pure, and potent;

9           “(viii) the Secretary has withdrawn or  
10          suspended the license of the reference  
11          product, for safety or effectiveness reasons,  
12          or has published a notice of opportunity  
13          for hearing to withdraw such license for  
14          safety or effectiveness reasons, or the Sec-  
15          retary has determined that the reference  
16          product has been withdrawn from sale for  
17          safety or effectiveness reasons; or

18          “(ix) the application contains an un-  
19          true statement of material fact; and  
20          provides the applicant with a detailed expla-  
21          nation for the decision.

22          “(B) DETERMINATIONS ON INTERCHANGE-  
23          ABILITY.—Subject to subparagraph (C) and  
24          paragraph (10), upon issuing a product license  
25          for a biological product under subparagraph

1 (A), the Secretary shall make and publish one  
2 of the following determinations:

3 “(i) Such product is interchangeable  
4 with the reference product for one or more  
5 specified conditions of use prescribed, rec-  
6 ommended, or suggested in the labeling of  
7 the biological product.

8 “(ii) Interchangeability has not been  
9 established.

10 “(C) DETERMINATION OF INTERCHANGE-  
11 ABILITY OF SUBSEQUENT BIOLOGICAL PROD-  
12 UCT.—If the Secretary determines that an ap-  
13 plication meets the approval requirements of  
14 subparagraph (A), and, prior to the issuance of  
15 a product license, the Secretary has made a de-  
16 termination of interchangeability of another bio-  
17 logical product and the reference product for  
18 which the exclusivity period under paragraph  
19 (10) has not expired, the Secretary shall—

20 “(i) issue the product license for the  
21 subsequent biological product; and

22 “(ii) defer issuing any determination  
23 of interchangeability as to the subsequent  
24 biological product and the reference prod-

1                   uct until the exclusivity period under para-  
2                   graph (10) has expired.

3                   “(5) POSTMARKETING STUDIES FOR APPLICA-  
4                   TIONS SUBMITTED UNDER PARAGRAPH (1).—If the  
5                   Secretary has agreed with the sponsor of the ref-  
6                   erence product, at the time of approval or any time  
7                   thereafter, that the sponsor shall conduct one or  
8                   more postmarketing safety studies, a person submit-  
9                   ting an application for a biological product under  
10                  paragraph (1) may agree with the Secretary to con-  
11                  duct a similar postmarketing safety study or studies  
12                  upon a reasonable showing that such study or stud-  
13                  ies would provide relevant information not available  
14                  from the studies on the reference product. The Sec-  
15                  retary shall not, as a condition of approval, propose  
16                  any additional postmarketing studies for such bio-  
17                  logical product.

18                  “(6) DESIGNATION OF OFFICIAL NAME.—If,  
19                  pursuant to section 508 of the Federal Food, Drug,  
20                  and Cosmetic Act, the Secretary determines that  
21                  designation of an official name for a comparable bio-  
22                  logical product is necessary or desirable in the inter-  
23                  ests of usefulness or simplicity, the Secretary shall  
24                  designate the same official name for the comparable  
25                  biological product as the Secretary designated for

1 the reference product. This paragraph shall not  
2 apply to products approved under paragraph (7).

3 “(7) OTHER APPROVAL PROVISIONS.—The Sec-  
4 retary shall approve, under the provisions of para-  
5 graph (4)(A), an application for a license submitted  
6 under paragraph (2), except that the Secretary shall  
7 approve such an application that would otherwise be  
8 disapproved by reason of one or more of subpara-  
9 graphs (A) through (E) of paragraph (4)(A), if the  
10 application and any other information available to  
11 the Secretary are sufficient to establish the safety,  
12 purity, and potency of the comparable biological  
13 product relative to the reference product for the pro-  
14 posed condition or conditions of use for such prod-  
15 uct.

16 “(8) ESTABLISHING INTERCHANGEABILITY FOR  
17 COMPARABLE BIOLOGICAL PRODUCTS.—

18 “(A) IN GENERAL.—In an original applica-  
19 tion or a supplement to an application under  
20 this subsection, an applicant may submit infor-  
21 mation to the Secretary to demonstrate the  
22 interchangeability of a comparable biological  
23 product and the reference product. An applicant  
24 may withdraw an interchangeability submission  
25 at any time. A request for an interchangeability

1 determination submitted after the filing of an  
2 application shall be considered a major amend-  
3 ment to the application. Nothing in this sub-  
4 section shall be construed to prohibit the Sec-  
5 retary from making a determination of inter-  
6 changeability at any time after approval.

7 “(B) GUIDANCE.—Within one year after  
8 enactment of the Access to Life-Saving Medi-  
9 cine Act, the Secretary shall issue guidance re-  
10 garding standards and requirements for inter-  
11 changeability. The Secretary may make deter-  
12 minations of interchangeability under para-  
13 graph (4)(B) prior to issuing guidance under  
14 this subparagraph.

15 “(9) INTERCHANGEABILITY LABELING FOR  
16 COMPARABLE BIOLOGICAL PRODUCTS.—Upon a de-  
17 termination of interchangeability, the Secretary, if  
18 requested by the applicant, shall provide for the  
19 label of the comparable biological product to include  
20 a statement that the biological product is inter-  
21 changeable with the reference product for the condi-  
22 tions of use prescribed, recommended, or suggested  
23 in the labeling for which interchangeability has been  
24 established.

25 “(10) EXCLUSIVITY.—

1           “(A) IN GENERAL.—Upon review of an ab-  
2           breviated biological product application relying  
3           on the same reference product for which a prior  
4           biological product has received a determination  
5           of interchangeability for any condition of use,  
6           the Secretary shall not make a determination  
7           under paragraph (4)(B) that the second or sub-  
8           sequent biological product is interchangeable for  
9           any condition of use, and no holder of a biologi-  
10          cal product license approved under subsection  
11          (a) shall manufacture, market, sell, or dis-  
12          tribute a rebranded interchangeable biological  
13          product, directly or indirectly, or authorize any  
14          other person to manufacture, market, sell, or  
15          distribute a rebranded interchangeable biologi-  
16          cal product, for any condition of use, until the  
17          earlier of—

18                   “(i) 180 days after the first commer-  
19                   cial marketing of the first interchangeable  
20                   comparable biological product to be ap-  
21                   proved as interchangeable for that ref-  
22                   erence product;

23                   “(ii) one year after—

24                           “(I) a final court decision on all  
25                           patents in suit in an action instituted

1 under paragraph (17)(C) against the  
2 applicant that submitted the applica-  
3 tion for the first approved inter-  
4 changeable comparable biological  
5 product; or

6 “(II) the dismissal with or with-  
7 out prejudice of an action instituted  
8 under paragraph (17)(C) against the  
9 applicant that submitted the applica-  
10 tion for the first approved inter-  
11 changeable comparable biological  
12 product; or

13 “(iii)(I) 36 months after approval of  
14 the first interchangeable comparable bio-  
15 logical product if the applicant has been  
16 sued under paragraph (17)(C) and such  
17 litigation is still ongoing within such 36-  
18 month period; or

19 “(II) one year after approval in the  
20 event that the first approved interchange-  
21 able comparable applicant has not been  
22 sued under paragraph (17)(C).

23 For purposes of this subparagraph, the term  
24 ‘final court decision’ means a final decision of  
25 a court from which no appeal (other than a pe-

1           tition to the United States Supreme Court for  
2           a writ of certiorari) has been or can be taken.

3           “(B) REBRANDED INTERCHANGEABLE BI-  
4           OLOGICAL PRODUCT.—For purposes of this sub-  
5           section, the term ‘rebranded interchangeable bi-  
6           ological product’—

7                   “(i) means any rebranded inter-  
8                   changeable version of the reference product  
9                   involved that the holder of the biological  
10                  product license approved under subsection  
11                  (a) for that reference product seeks to  
12                  commence marketing, selling, or distrib-  
13                  uting, directly or indirectly; and

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

16                   “(I) by an entity eligible for ex-  
17                   clusivity with respect to such product  
18                   under this paragraph; or

19                   “(II) after expiration of any ex-  
20                   clusivity with respect to such product  
21                   under this paragraph.

22           “(11) HEARING.—If the Secretary decides to  
23           disapprove an abbreviated biological product applica-  
24           tion, the Secretary shall give the applicant notice of  
25           an opportunity for a hearing before the Secretary on

1 the question of whether such application is approv-  
2 able. If the applicant elects to accept the opportunity  
3 for hearing by written request within thirty days  
4 after such notice, such hearing shall commence not  
5 more than ninety days after the expiration of such  
6 thirty days unless the Secretary and the applicant  
7 otherwise agree. Any such hearing shall thereafter  
8 be conducted on an expedited basis, and the Sec-  
9 retary's order thereon shall be issued within ninety  
10 days after the date fixed by the Secretary for filing  
11 final briefs.

12 “(12) FINAL ACTION DATE.—

13 “(A) IN GENERAL.—The Secretary shall  
14 take a final action on an abbreviated biological  
15 product application by the date that is 8 cal-  
16 endar months following the sponsor's submis-  
17 sion of such application, or 180 days following  
18 the Secretary's notification to the applicant that  
19 its application has been accepted for filing,  
20 whichever is earlier.

21 “(B) EXTENSION.—The final action date  
22 provided by subparagraph (A) with respect to  
23 an application may be extended for such period  
24 of time as is agreed to by the Secretary and the  
25 applicant in a jointly executed written agree-

1           ment that is counter-signed by the Secretary  
2           and the applicant no later than 30 days prior  
3           to such date.

4           “(13) REQUEST FOR DELAY OF FINAL AC-  
5           TION.—Notwithstanding paragraph (18) or any  
6           other provision of law, the Secretary shall not fail or  
7           refuse to take a final action on an abbreviated bio-  
8           logical product application by the final action date  
9           on the basis that a person, other than the com-  
10          parable biological product applicant, has requested  
11          (in a petition or otherwise) that the Secretary refuse  
12          to take or otherwise defer such final action, and no  
13          court shall enjoin the Secretary from taking final ac-  
14          tion or stay the effect of final action previously  
15          taken by the Secretary, except by issuance of a per-  
16          manent injunction based upon an express finding of  
17          clear and convincing evidence that the person seek-  
18          ing to have the Secretary refuse to take or otherwise  
19          to defer final action by the final action date—

20                   “(A) has prevailed on the merits of the  
21                   person’s complaint against the Secretary;

22                   “(B) will suffer imminent and actual irrepar-  
23                   able injury, constituting more than irrecover-  
24                   able economic loss, and that also will threaten

1           imminent destruction of such person’s business;  
2           and

3                   “(C) has an interest that outweighs the  
4           overwhelming interest that the public has in ob-  
5           taining prompt access to a comparable biologi-  
6           cal product.

7           “(14) REPORT ON EXTENSIONS OF FINAL AC-  
8           TION DATE.—The Secretary shall prepare and sub-  
9           mit to the President, the Committee on Energy and  
10          Commerce of the House of Representatives, and the  
11          Committee on Health, Education, Labor, and Pen-  
12          sions of the Senate a report regarding any jointly  
13          executed written agreement to extend the final ac-  
14          tion date under this Act within 15 calendar days  
15          after the joint execution of any such written agree-  
16          ment.

17                   “(15) REPORT ON FAILURE TO TAKE FINAL AC-  
18           TION.—The Secretary shall prepare and submit an-  
19           nually to the President, the Committee on Energy  
20           and Commerce of the House of Representatives, and  
21           the Committee on Health, Education, Labor, and  
22           Pensions of the Senate a report detailing the specific  
23           and particularized reasons enumerated by the re-  
24           viewing division for each instance of the Secretary’s

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

3 “(16) REGULATIONS.—The Secretary shall es-  
4 tablish, by regulation within 2 years after the date  
5 of the enactment of this subsection, requirements for  
6 the efficient review, approval, suspension, and rev-  
7 ocation of abbreviated biological product applications  
8 under this subsection.

9 “(17) PATENTS.—

10 “(A) REQUEST FOR PATENT INFORMA-  
11 TION.—

12 “(i) IN GENERAL.—At any time, in-  
13 cluding at the initial stages of develop-  
14 ment, an applicant or a prospective appli-  
15 cant under this subsection may send a  
16 written request for patent information to  
17 the holder of the approved application for  
18 the reference product. The holder of the  
19 approved application for the reference  
20 product shall, not later than 60 days after  
21 the date on which the holder receives the  
22 request, provide to the applicant or pro-  
23 spective applicant a list of all those patents  
24 owned by, or licensed to, the holder of the  
25 approved application that the holder be-

1           lieves in good faith relate to the reference  
2           product, including patents that claim the  
3           approved biological product, any method of  
4           using such product, any component of such  
5           product, or any method or process of man-  
6           ufacturing such product or component.

7           “(ii) COSTS OF COMPLYING WITH RE-  
8           QUEST.—The application holder may de-  
9           mand payment of not more than \$1,000 to  
10          offset the cost of responding to the request  
11          for information.

12          “(iii) UPDATES.—For a period of two  
13          years beginning on the date on which the  
14          holder of the approved application for the  
15          reference product receives the request for  
16          information, the holder shall send to the  
17          applicant or prospective applicant updates  
18          of its response to the request for informa-  
19          tion by identifying all relevant patents  
20          issued or licensed to the holder after the  
21          initial response under clause (i). Any such  
22          update must be provided, in the case of a  
23          new patent, not later than 30 days after  
24          the date on which the patent is issued and,  
25          in the case of a license, not later than 30

1 days after the date on which the holder ob-  
2 tains the license.

3 “(iv) ADDITIONAL REQUESTS.—The  
4 applicant may submit additional requests  
5 for patent information, subject to the re-  
6 quirements of this paragraph, at any time.

7 “(B) PATENT NOTIFICATIONS.—At any  
8 time after submitting an application under this  
9 subsection, the applicant may provide a notice  
10 of the application with respect to any one or  
11 more patents identified by the holder of the ref-  
12 erence product pursuant to subparagraph (A).  
13 An applicant may submit additional notices at  
14 any time, and each notice shall be subject to  
15 the provisions of this subparagraph. Each no-  
16 tice shall—

17 “(i) be sent to the holder of the ap-  
18 proved application for the reference prod-  
19 uct and to the owner of any patent identi-  
20 fied by the holder pursuant to subpara-  
21 graph (A);

22 “(ii) include a detailed statement of  
23 the factual and legal bases for the appli-  
24 cant’s belief that the patents included in  
25 the notice are invalid, are unenforceable, or

1 will not be infringed by the commercial  
2 sale of the product for which approval is  
3 being sought under this subsection; and

4 “(iii) identify 1 or more judicial dis-  
5 tricts in which the applicant consents to  
6 such suit being brought.

7 “(C) ACTION FOR INFRINGEMENT.—With-  
8 in 45 days after the date on which the holder  
9 of the approved application for the reference  
10 product, or the owner of a patent, receives a no-  
11 tice under subparagraph (B), the holder or pat-  
12 ent owner may bring an action for infringement  
13 only with respect to the patent or patents in-  
14 cluded in the notice, and only in a judicial dis-  
15 trict identified pursuant to subparagraph  
16 (B)(iii).

17 “(D) LIMITATION ON DECLARATORY JUDG-  
18 MENT ACTIONS.—With respect to any patent re-  
19 lating to a product that is the subject of an ap-  
20 plication under this subsection, the recipient of  
21 a notice under subparagraph (B) with respect  
22 to that application may not, prior to the com-  
23 mercial marketing of the product, bring any ac-  
24 tion under section 2201 of title 28, United  
25 States Code, for a declaration of infringement,

1 validity, or enforceability of any such patent  
2 that was not identified in the notice. With re-  
3 spect to any such patent identified in the no-  
4 tice, any such action may, notwithstanding  
5 chapter 87 of title 28, United States Code, be  
6 brought only in a judicial district identified in  
7 the notice.

8 “(E) DISCRETION OF APPLICANTS.—An  
9 applicant or prospective applicant for a com-  
10 parable biological product under this subsection  
11 may not be compelled, by court order or other-  
12 wise, to initiate the procedures set forth in this  
13 paragraph. Nothing in this paragraph requires  
14 an applicant or a prospective applicant to in-  
15 voke the procedures set forth in this paragraph.

16 “(18) PETITIONS AND CIVIL ACTIONS REGARD-  
17 ING APPROVAL OF CERTAIN APPLICATIONS.—

18 “(A) IN GENERAL.—With respect to a  
19 pending application submitted under paragraph  
20 (1) or (2), if a petition is submitted to the Sec-  
21 retary that seeks to have the Secretary take, or  
22 refrain from taking, any form of action relating  
23 to the approval of the application, including a  
24 delay in the effective date of the application,

1 the following applies, subject to subparagraph  
2 (E):

3 “(i)(I) The Secretary may not, on the  
4 basis of the petition, delay approval of the  
5 application unless the Secretary deter-  
6 mines, within 30 days after receiving the  
7 petition, that a delay is necessary to pro-  
8 tect the public health. Consideration of a  
9 petition shall be separate and apart from  
10 the review and approval of the application.

11 “(II) With respect to a determination  
12 by the Secretary under subclause (I) that  
13 a delay is necessary to protect the public  
14 health:

15 “(aa) The Secretary shall publish  
16 on the Internet site of the Food and  
17 Drug Administration a statement pro-  
18 viding the reasons underlying the de-  
19 termination.

20 “(bb) Not later than 10 days  
21 after making the determination, the  
22 Secretary shall provide notice to the  
23 sponsor of the application and an op-  
24 portunity for a meeting with the Com-

1           missioner to discuss the determina-  
2           tion.

3           “(ii) The Secretary shall take final  
4           agency action on the petition not later  
5           than 180 days after the date on which the  
6           petition is submitted. The Secretary shall  
7           not extend such period, even with the con-  
8           sent of the petitioner, for any reason, in-  
9           cluding based upon the submission of com-  
10          ments relating to the petition or supple-  
11          mental information supplied by the peti-  
12          tioner.

13          “(iii) The Secretary may not consider  
14          the petition for review unless it is signed  
15          and contains the following verification: ‘I  
16          certify that, to my best knowledge and be-  
17          lief: (a) this petition includes all informa-  
18          tion and views upon which the petition re-  
19          lies; (b) this petition includes representa-  
20          tive data and/or information known to the  
21          petitioner which are unfavorable to the pe-  
22          tition; and (c) I have taken reasonable  
23          steps to ensure that any representative  
24          data and/or information which are unfavor-  
25          able to the petition were disclosed to me.

1 I further certify that the information upon  
2 which I have based the action requested  
3 herein first became known to the party on  
4 whose behalf this petition is submitted on  
5 or about the following date:  
6 \_\_\_\_\_ . I received or expect to  
7 receive payments, including cash and other  
8 forms of consideration, from the following  
9 persons or organizations to file this peti-  
10 tion: \_\_\_\_\_. I verify under  
11 penalty of perjury that the foregoing is  
12 true and correct.’.

13 “(B) EXHAUSTION OF ADMINISTRATIVE  
14 REMEDIES.—

15 “(i) FINAL AGENCY ACTION WITHIN  
16 180 DAYS.—The Secretary shall be consid-  
17 ered to have taken final agency action on  
18 a petition referred to in subparagraph (A)  
19 if—

20 “(I) during the 180-day period  
21 referred to in clause (ii) of such sub-  
22 paragraph, the Secretary makes a  
23 final decision within the meaning of  
24 section 10.45(d) of title 21, Code of

1 Federal Regulations (or any successor  
2 regulations); or

3 “(II) such period expires without  
4 the Secretary having made such a  
5 final decision.

6 “(ii) DISMISSAL OF CERTAIN CIVIL  
7 ACTIONS.—If a civil action is filed with re-  
8 spect to a petition referred to in subpara-  
9 graph (A) before final agency action within  
10 the meaning of clause (i) has occurred, the  
11 court shall dismiss the action for failure to  
12 exhaust administrative remedies.

13 “(C) APPLICABILITY OF CERTAIN REGULA-  
14 TIONS.—The provisions of this section are in  
15 addition to the requirements for the submission  
16 of a petition to the Secretary that apply under  
17 section 10.30 or 10.35 of title 21, Code of Fed-  
18 eral Regulations (or any successor regulations).

19 “(D) ANNUAL REPORT ON DELAYS IN AP-  
20 PROVALS PER PETITIONS.—The Secretary shall  
21 annually submit to the Congress a report that  
22 specifies—

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

1           “(ii) the number of such applications  
2           whose effective dates were delayed by peti-  
3           tions referred to in subparagraph (A) dur-  
4           ing such period; and

5           “(iii) the number of days by which the  
6           applications were so delayed.

7           “(E) EXCEPTION.—This paragraph does  
8           not apply to a petition that is made by the  
9           sponsor of an application under this subsection  
10          and that seeks only to have the Secretary take  
11          or refrain from taking any form of action with  
12          respect to that application.

13          “(F) DEFINITION.—For purposes of this  
14          paragraph, the term ‘petition’ includes any re-  
15          quest to the Secretary, without regard to  
16          whether the request is characterized as a peti-  
17          tion.”.

18          (b) ADDITIONAL AMENDMENTS.—

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

21                         (A) in paragraph (2)—

22                                 (i) by striking “or” at the end of sub-  
23                                 paragraph (A);

24                                 (ii) by adding “or” at the end of sub-  
25                                 paragraph (B);

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

3 “(C) a notice described in section  
4 351(k)(17)(B) of the Public Health Service Act, but  
5 only with respect to a patent identified in such no-  
6 tice,”; and

7 (iv) in the matter following subpara-  
8 graph (C) (as inserted by clause (iii) of  
9 this subparagraph), by inserting before the  
10 period the following: “, or if the notice de-  
11 scribed in subparagraph (C) is provided in  
12 connection with an application to obtain a  
13 license to engage in the commercial manu-  
14 facture, use, or sale of a biological product  
15 claimed in a patent or the use of which is  
16 claimed in a patent before the expiration of  
17 such patent”; and

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

20 “(6) (A) This paragraph applies, in lieu of paragraph  
21 (4), in the case of a patent—

22 “(i) which is disclosed in a response to a  
23 request for patent information pursuant to sub-  
24 paragraph (A) of section 351(k)(17) of the  
25 Public Health Service Act;

1           “(ii) with respect to which a notice was  
2           provided pursuant to subparagraph (B) of such  
3           section; and

4           “(iii) for which an action for infringement  
5           of the patent—

6                   “(I) was brought after the expiration  
7                   of the 45-day period described in subpara-  
8                   graph (C) of such section; or

9                   “(II) was brought before the expira-  
10                  tion of the 45-day period described in sub-  
11                  clause (I), but which was dismissed with-  
12                  out prejudice or was not prosecuted to  
13                  judgment in good faith.

14           “(B) In an action for infringement of a patent  
15           described in subparagraph (A), the sole and exclu-  
16           sive remedy that may be granted by a court, upon  
17           a finding that the person who submitted the notice  
18           described in subparagraph (A)(ii) infringed the pat-  
19           ent, or that any person induced or contributed to in-  
20           fringement of the patent, shall be a reasonable roy-  
21           alty.

22           “(C) The owner of a patent that should have  
23           been disclosed in response to a request for patent in-  
24           formation made by an applicant pursuant to sub-  
25           paragraph (A)(i) of section 351(k)(17) of the Public

1 Health Service Act, but that was not timely dis-  
2 closed under that subparagraph, may not bring an  
3 action under this section for infringement of that  
4 patent.”.

5 (2) CONFORMING AMENDMENTS.—

6 (A) TITLE 28.—Section 2201(b) of title  
7 28, United States Code, is amended by insert-  
8 ing before the period the following: “, or section  
9 351 of the Public Health Service Act”.

10 (B) PUBLIC HEALTH SERVICE ACT.—Sub-  
11 jection (j) of section 351 of the Public Health  
12 Service Act (42 U.S.C. 262) is amended by in-  
13 serting “or subsection (k)” after “subsection  
14 (a)”.

○