

110TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To amend the Public Health Service Act to establish a pathway for the licensure of biosimilar biological products, to promote innovation in the life sciences, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

Mr. KENNEDY (for himself, Mr. HATCH, Mrs. CLINTON, and Mr. ENZI) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**A BILL**

To amend the Public Health Service Act to establish a pathway for the licensure of biosimilar biological products, to promote innovation in the life sciences, 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 “Biologics Price Com-  
5 petition and Innovation Act of 2007”.

1 **SEC. 2. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL**  
2 **PRODUCTS.**

3 (a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-  
4 SIMILAR OR INTERCHANGEABLE.—Section 351 of the  
5 Public Health Service Act (42 U.S.C. 262) is amended—

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

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

10 “(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-  
11 SIMILAR OR INTERCHANGEABLE.—

12 “(1) IN GENERAL.—Any person may submit an  
13 application for licensure of a biological product  
14 under this subsection.

15 “(2) CONTENT.—

16 “(A) IN GENERAL.—

17 “(i) REQUIRED INFORMATION.—An  
18 application submitted under this subsection  
19 shall include information demonstrating  
20 that—

21 “(I) the biological product is bio-  
22 similar to a reference product based  
23 upon data derived from—

24 “(aa) analytical studies that  
25 demonstrate that the biological  
26 product is highly similar to the

1 reference product notwith-  
2 standing minor differences in  
3 clinically inactive components;  
4 “(bb) animal studies; and  
5 “(cc) a clinical study or  
6 studies (including the assessment  
7 of immunogenicity and phar-  
8 macokinetics or  
9 pharmacodynamics) that are—  
10 “(AA) sufficient to  
11 demonstrate safety, purity,  
12 and potency in 1 or more  
13 appropriate conditions of use  
14 for which the reference  
15 product is licensed and in-  
16 tended to be used and for  
17 which licensure is sought for  
18 the biological product; and  
19 “(BB) designed to  
20 avoid needlessly duplicative  
21 or unethical clinical testing;  
22 “(II) the biological product and  
23 reference product utilize the same  
24 mechanism or mechanisms of action  
25 for the condition or conditions of use

1 prescribed, recommended, or sug-  
2 gested in the proposed labeling, but  
3 only to the extent the mechanism or  
4 mechanisms of action are known for  
5 the reference product;

6 “(III) the condition or conditions  
7 of use prescribed, recommended, or  
8 suggested in the labeling proposed for  
9 the biological product have been pre-  
10 viously approved for the reference  
11 product;

12 “(IV) the route of administra-  
13 tion, the dosage form, and the  
14 strength of the biological product are  
15 the same as those of the reference  
16 product; and

17 “(V) the facility in which the bio-  
18 logical product is manufactured, proc-  
19 essed, packed, or held meets stand-  
20 ards designed to assure that the bio-  
21 logical product continues to be safe,  
22 pure, and potent.

23 “(ii) DETERMINATION BY SEC-  
24 RETARY.—The Secretary may determine,  
25 in the Secretary’s discretion, that an ele-

1                   ment described in clause (i)(I) is unneces-  
2                   sary in an application submitted under this  
3                   subsection.

4                   “(iii) ADDITIONAL INFORMATION.—  
5                   An application submitted under this sub-  
6                   section may include—

7                   “(I) at the applicant’s option,  
8                   publicly-available information regard-  
9                   ing the Secretary’s previous deter-  
10                  mination that the reference product is  
11                  safe, pure, and potent; and

12                  “(II) any additional information  
13                  in support of the application, includ-  
14                  ing publicly-available information with  
15                  respect to the reference product or an-  
16                  other biological product.

17                  “(B) INTERCHANGEABILITY.—An applica-  
18                  tion (or a supplement to an application) sub-  
19                  mitted under this subsection may include infor-  
20                  mation demonstrating that the biological prod-  
21                  uct is interchangeable with the reference prod-  
22                  uct.

23                  “(3) EVALUATION BY SECRETARY.—Upon re-  
24                  view of an application (or a supplement to an appli-  
25                  cation) submitted under this subsection, the Sec-

1       retary shall license the biological product under this  
2       subsection if the Secretary determines that the infor-  
3       mation submitted in the application (or the supple-  
4       ment) is sufficient to show that the biological prod-  
5       uct—

6               “(A) is biosimilar to the reference product;

7               or

8               “(B) is interchangeable with the reference  
9       product.

10       “(4) SAFETY STANDARDS FOR DETERMINING  
11       INTERCHANGEABILITY.—Upon review of an applica-  
12       tion submitted under this subsection or any supple-  
13       ment to such application, the Secretary shall deter-  
14       mine the biological product to be interchangeable  
15       with the reference product if the Secretary deter-  
16       mines that the information submitted in the applica-  
17       tion (or a supplement to such application) is suffi-  
18       cient to show that—

19               “(A) the biological product—

20                       “(i) is biosimilar to the reference  
21                       product; and

22                       “(ii) can be expected to produce the  
23                       same clinical result as the reference prod-  
24                       uct in any given patient; and

1           “(B) for a biological product that is ad-  
2           ministered more than once to an individual, the  
3           risk in terms of safety or diminished efficacy of  
4           alternating or switching between use of the bio-  
5           logical product and the reference product is not  
6           greater than the risk of using the reference  
7           product without such alternation or switch.

8           “(5) GENERAL RULES.—

9           “(A) ONE REFERENCE PRODUCT PER AP-  
10          PLICATION.—A biological product, in an appli-  
11          cation submitted under this subsection, may not  
12          be evaluated against more than 1 reference  
13          product.

14          “(B) REVIEW.—An application submitted  
15          under this subsection shall be reviewed by the  
16          division within the Food and Drug Administra-  
17          tion that is responsible for the review and ap-  
18          proval of the application under which the ref-  
19          erence product is licensed.

20          “(C) RISK EVALUATION AND MITIGATION  
21          STRATEGIES.—The authority of the Secretary  
22          with respect to risk evaluation and mitigation  
23          strategies under the Federal Food, Drug, and  
24          Cosmetic Act shall apply to biological products  
25          licensed under this subsection in the same man-

1           ner as such authority applies to biological prod-  
2           ucts licensed under subsection (a).

3           “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-  
4           ABLE BIOLOGICAL PRODUCT.—Upon review of an  
5           application submitted under this subsection relying  
6           on the same reference product for which a prior bio-  
7           logical product has received a determination of inter-  
8           changeability for any condition of use, the Secretary  
9           shall not make a determination under paragraph (4)  
10          that the second or subsequent biological product is  
11          interchangeable for any condition of use until the  
12          earlier of—

13                 “(A) 1 year after the first commercial  
14                 marketing of the first interchangeable bio-  
15                 similar biological product to be approved as  
16                 interchangeable for that reference product;

17                 “(B) 18 months after—

18                         “(i) a final court decision on all pat-  
19                         ents in suit in an action instituted under  
20                         subsection (l)(6) against the applicant that  
21                         submitted the application for the first ap-  
22                         proved interchangeable biosimilar biological  
23                         product; or

24                         “(ii) the dismissal with or without  
25                         prejudice of an action instituted under sub-



1 section (l)(6) against the applicant that  
2 submitted the application for the first ap-  
3 proved interchangeable biosimilar biological  
4 product; or

5 “(C)(i) 42 months after approval of the  
6 first interchangeable biosimilar biological prod-  
7 uct if the applicant that submitted such appli-  
8 cation has been sued under subsection (l)(6)  
9 and such litigation is still ongoing within such  
10 36-month period; or

11 “(ii) 18 months after approval of the first  
12 interchangeable biosimilar biological product if  
13 the applicant that submitted such application  
14 has not been sued under subsection (l)(6).

15 For purposes of this paragraph, the term ‘final court  
16 decision’ means a final decision of a court from  
17 which no appeal (other than a petition to the United  
18 States Supreme Court for a writ of certiorari) has  
19 been or can be taken.

20 “(7) EXCLUSIVITY FOR REFERENCE PROD-  
21 UCT.—

22 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-  
23 PPLICATION APPROVAL.—Approval of an applica-  
24 tion under this subsection may not be made ef-  
25 fective by the Secretary until the date that is

1           12 years after the date on which the reference  
2           product was first licensed under subsection (a).

3           “(B) FILING PERIOD.—An application  
4           under this subsection may not be submitted to  
5           the Secretary until the date that is 4 years  
6           after the date on which the reference product  
7           was first licensed under subsection (a).

8           “(8) GUIDANCE DOCUMENTS.—

9           “(A) IN GENERAL.—The Secretary may,  
10          after opportunity for public comment, issue  
11          guidance in accordance, except as provided in  
12          subparagraph (B)(i), with section 701(h) of the  
13          Federal Food, Drug, and Cosmetic Act with re-  
14          spect to the process for the submission of appli-  
15          cations for, and licensure of, a biological prod-  
16          uct under this subsection. Any such guidance  
17          may be general or specific.

18          “(B) PUBLIC COMMENT.—

19          “(i) IN GENERAL.—The Secretary  
20          shall provide the public an opportunity to  
21          comment on any proposed guidance issued  
22          under subparagraph (A) before issuing  
23          final guidance.

24          “(ii) INPUT REGARDING MOST VALU-  
25          ABLE GUIDANCE.—The Secretary shall es-

1           tablish a process through which the public  
2           may provide the Secretary with input re-  
3           garding priorities for issuing guidance.

4           “(C) NO REQUIREMENT FOR APPLICATION  
5           CONSIDERATION.—The issuance (or non-  
6           issuance) of guidance under subparagraph (A)  
7           shall not preclude the review of, or action on,  
8           an application submitted under this subsection.

9           “(D) REQUIREMENT FOR PRODUCT CLASS-  
10          SPECIFIC GUIDANCE.—If the Secretary issues  
11          product class-specific guidance under subpara-  
12          graph (A), such guidance shall include a de-  
13          scription of—

14                 “(i) the criteria that the Secretary will  
15                 use to determine whether a biological prod-  
16                 uct is highly similar to a reference product  
17                 in such product class; and

18                 “(ii) the criteria, if available, that the  
19                 Secretary will use to determine whether a  
20                 biological product meets the standards de-  
21                 scribed in paragraph (4).

22          “(E) CERTAIN PRODUCT CLASSES.—

23                 “(i) GUIDANCE.—The Secretary may  
24                 indicate in a guidance document that the  
25                 science and experience, as of the date of

1           such guidance, with respect to a product or  
2           product class (not including any recom-  
3           binant protein) does not allow approval of  
4           an application for a license as provided  
5           under this subsection for such product or  
6           product class.

7           “(ii) MODIFICATION OR REVERSAL.—  
8           The Secretary may issue a subsequent  
9           guidance document under subparagraph  
10          (A) to modify or reverse a guidance docu-  
11          ment under clause (i).

12          “(iii) NO EFFECT ON ABILITY TO  
13          DENY LICENSE.—Clause (i) shall not be  
14          construed to require the Secretary to ap-  
15          prove a product with respect to which the  
16          Secretary has not indicated in a guidance  
17          document that the science and experience,  
18          as described in clause (i), does not allow  
19          approval of such an application.

20          “(l) PATENTS.—

21                  “(1) CONFIDENTIAL ACCESS TO SUBSECTION  
22          (k) APPLICATION.—

23                  “(A) APPLICATION OF PARAGRAPH.—Un-  
24          less otherwise agreed to by a person that sub-  
25          mits an application under subsection (k) (re-

1           ferred to in this subsection as the ‘subsection  
2           (k) applicant’) and the sponsor of the applica-  
3           tion for the reference product (referred to in  
4           this paragraph as the ‘reference product spon-  
5           sor’), the provisions of this paragraph shall  
6           apply to the exchange of information described  
7           in this subsection.

8                   “(B) IN GENERAL.—

9                           “(i) PROVISION OF CONFIDENTIAL IN-  
10                           FORMATION.—When a subsection (k) ap-  
11                           plicant submits an application under sub-  
12                           section (k), such applicant shall provide to  
13                           the persons described in clause (ii), subject  
14                           to the terms of this paragraph, confidential  
15                           access to the information required to be  
16                           produced pursuant to paragraph (2) and  
17                           any other information that the subsection  
18                           (k) applicant determines, in its sole discre-  
19                           tion, to be appropriate (referred to in this  
20                           subsection as the ‘confidential informa-  
21                           tion’).

22                           “(ii) RECIPIENTS OF INFORMATION.—

23                           The persons described in this clause are  
24                           the following:

1                   “(I) OUTSIDE COUNSEL.—One or  
2                   more attorneys designated by the ref-  
3                   erence product sponsor who are em-  
4                   ployees of an entity other than the  
5                   reference product sponsor (referred to  
6                   in this paragraph as the ‘outside  
7                   counsel’), provided that such attor-  
8                   neys do not engage, formally or infor-  
9                   mally, in patent prosecution relevant  
10                  or related to the reference product.

11                  “(II) IN-HOUSE COUNSEL.—One  
12                  attorney that represents the reference  
13                  product sponsor who is an employee  
14                  of the reference product sponsor, pro-  
15                  vided that such attorney does not en-  
16                  gage, formally or informally, in patent  
17                  prosecution relevant or related to the  
18                  reference product.

19                  “(C) LIMITATION ON DISCLOSURE.—No  
20                  person that receives confidential information  
21                  pursuant to subparagraph (B) shall disclose  
22                  any confidential information to any other per-  
23                  son or entity, including the reference product  
24                  sponsor employees, outside scientific consult-  
25                  ants, or other outside counsel retained by the

1 reference product sponsor, without the prior  
2 written consent of the subsection (k) applicant,  
3 which shall not be unreasonably withheld.

4 “(D) USE OF CONFIDENTIAL INFORMA-  
5 TION.—Confidential information shall be used  
6 for the sole and exclusive purpose of deter-  
7 mining, with respect to each patent assigned to  
8 or exclusively licensed by the reference product  
9 sponsor, whether a claim of patent infringement  
10 could reasonably be asserted if the subsection  
11 (k) applicant engaged in the manufacture, use,  
12 offering for sale, sale, or importation into the  
13 United States of the biological product that is  
14 the subject of the application under subsection  
15 (k).

16 “(E) OWNERSHIP OF CONFIDENTIAL IN-  
17 FORMATION.—The confidential information dis-  
18 closed under this paragraph is, and shall re-  
19 main, the property of the subsection (k) appli-  
20 cant. By providing the confidential information  
21 pursuant to this paragraph, the subsection (k)  
22 applicant does not provide the reference product  
23 sponsor or the outside counsel any interest in or  
24 license to use the confidential information, for

1 purposes other than those specified in subpara-  
2 graph (D).

3 “(F) EFFECT OF INFRINGEMENT AC-  
4 TION.—In the event that the reference product  
5 sponsor files a patent infringement suit, the use  
6 of confidential information shall continue to be  
7 governed by the terms of this paragraph until  
8 such time as a court enters a protective order  
9 regarding the information. Upon entry of such  
10 order, the subsection (k) applicant may redesign-  
11 nate confidential information in accordance  
12 with the terms of that order. No confidential in-  
13 formation shall be included in any publicly-  
14 available complaint or other pleading. In the  
15 event that the reference product sponsor does  
16 not file an infringement action by the date spec-  
17 ified in paragraph (6), the reference product  
18 sponsor shall return or destroy all confidential  
19 information received under this paragraph, pro-  
20 vided that if the reference product sponsor opts  
21 to destroy such information, it will confirm de-  
22 struction in writing to the subsection (k) appli-  
23 cant.

24 “(G) RULE OF CONSTRUCTION.—Nothing  
25 in this paragraph shall be construed—



1                   “(i) as an admission by the subsection  
2                   (k) applicant regarding the validity, en-  
3                   forceability, or infringement of any patent;  
4                   or

5                   “(ii) an agreement or admission by  
6                   the subsection (k) applicant with respect to  
7                   the competency, relevance, or materiality  
8                   of any confidential information.

9                   “(H) EFFECT OF VIOLATION.—The disclo-  
10                  sure of any confidential information in violation  
11                  of this paragraph shall be deemed to cause the  
12                  subsection (k) applicant to suffer irreparable  
13                  harm for which there is no adequate legal rem-  
14                  edy and the court shall consider immediate in-  
15                  junctive relief to be an appropriate and nec-  
16                  essary remedy for any violation or threatened  
17                  violation of this paragraph.

18                  “(2) SUBSECTION (k) APPLICATION INFORMA-  
19                  TION.—Not later than 20 days after the Secretary  
20                  notifies the subsection (k) applicant that the applica-  
21                  tion has been accepted for review, the subsection (k)  
22                  applicant—

23                  “(A) shall provide to the reference product  
24                  sponsor a copy of the application submitted to  
25                  the Secretary under subsection (k), and such

1 other information that describes the process or  
2 processes used to manufacture the biological  
3 product that is the subject of such application;  
4 and

5 “(B) may provide to the reference product  
6 sponsor additional information requested by or  
7 on behalf of the reference product sponsor.

8 “(3) LIST AND DESCRIPTION OF PATENTS.—

9 “(A) LIST BY REFERENCE PRODUCT SPON-  
10 SOR.—Not later than 60 days after the receipt  
11 of the application and information under para-  
12 graph (2), the reference product sponsor shall  
13 provide to the subsection (k) applicant—

14 “(i) a list of patents for which the ref-  
15 erence product sponsor believes a claim of  
16 patent infringement could reasonably be  
17 asserted by the reference product sponsor  
18 if a person not licensed by the reference  
19 product sponsor engaged in the making,  
20 using, offering to sell, selling, or importing  
21 into the United States of the biological  
22 product that is the subject of the sub-  
23 section (k) application; and

24 “(ii) an identification of the patents  
25 on such list that the reference product

1 sponsor would be prepared to license to the  
2 subsection (k) applicant.

3 “(B) LIST AND DESCRIPTION BY SUB-  
4 SECTION (k) APPLICANT.—Not later than 60  
5 days after receipt of the list under subpara-  
6 graph (A), the subsection (k) applicant—

7 “(i) may provide to the reference  
8 product sponsor a list of patents to which  
9 the subsection (k) applicant believes a  
10 claim of patent infringement could reason-  
11 ably be asserted by the reference product  
12 sponsor if a person not licensed by the ref-  
13 erence product sponsor engaged in the  
14 making, using, offering to sell, selling, or  
15 importing into the United States of the bi-  
16 ological product that is the subject of the  
17 subsection (k) application;

18 “(ii) shall provide to the reference  
19 product sponsor, with respect to each pat-  
20 ent listed by the reference product sponsor  
21 under subparagraph (A) or listed by the  
22 subsection (k) applicant under clause (i)—

23 “(I) a detailed statement that de-  
24 scribes, on a claim by claim basis, the  
25 factual and legal basis of the opinion

1 of the subsection (k) applicant that  
2 such patent is invalid, unenforceable,  
3 or will not be infringed by the com-  
4 mercial marketing of the biological  
5 product that is the subject of the sub-  
6 section (k) application; or

7 “(II) a statement that the sub-  
8 section (k) applicant does not intend  
9 to begin commercial marketing of the  
10 biological product before the date that  
11 such patent expires; and

12 “(iii) shall provide to the reference  
13 product sponsor a response regarding each  
14 patent identified by the reference product  
15 sponsor under subparagraph (A)(ii).

16 “(C) DESCRIPTION BY REFERENCE PROD-  
17 UCT SPONSOR.—Not later than 60 days after  
18 receipt of the list and statement under subpara-  
19 graph (B), the reference product sponsor shall  
20 provide to the subsection (k) applicant a de-  
21 tailed statement that describes, with respect to  
22 each patent described in subparagraph  
23 (B)(ii)(I), on a claim by claim basis, the factual  
24 and legal basis of the opinion of the reference  
25 product sponsor that such patent will be in-

1 fringed by the commercial marketing of the bio-  
2 logical product that is the subject of the sub-  
3 section (k) application and a response to the  
4 statement concerning validity and enforceability  
5 provided under subparagraph (B)(ii)(I).

6 “(4) PATENT RESOLUTION NEGOTIATIONS.—

7 “(A) IN GENERAL.—After receipt by the  
8 subsection (k) applicant of the statement under  
9 paragraph (3)(C), the reference product spon-  
10 sor and the subsection (k) applicant shall en-  
11 gage in good faith negotiations to agree on  
12 which, if any, patents listed under paragraph  
13 (3) by the subsection (k) applicant or the ref-  
14 erence product sponsor shall be the subject of  
15 an action for patent infringement under para-  
16 graph (6).

17 “(B) FAILURE TO REACH AGREEMENT.—

18 If, within 15 days of beginning negotiations  
19 under subparagraph (A), the subsection (k) ap-  
20 plicant and the reference product sponsor fail to  
21 agree on a final and complete list of which, if  
22 any, patents listed under paragraph (3) by the  
23 subsection (k) applicant or the reference prod-  
24 uct sponsor shall be the subject of an action for  
25 patent infringement under paragraph (6), the

1 provisions of paragraph (5) shall apply to the  
2 parties.

3 “(5) PATENT RESOLUTION IF NO AGREE-  
4 MENT.—

5 “(A) NUMBER OF PATENTS.—The sub-  
6 section (k) applicant shall notify the reference  
7 product sponsor of the number of patents that  
8 such applicant will provide to the reference  
9 product sponsor under subparagraph (B)(i)(I).

10 “(B) EXCHANGE OF PATENT LISTS.—

11 “(i) IN GENERAL.—On a date agreed  
12 to by the subsection (k) applicant and the  
13 reference product sponsor, but in no case  
14 later than 5 days after the subsection (k)  
15 application notifies the reference product  
16 sponsor under subparagraph (A), the sub-  
17 section (k) applicant and the reference  
18 product sponsor shall simultaneously ex-  
19 change—

20 “(I) the list of patents that the  
21 subsection (k) applicant believes  
22 should be the subject of an action for  
23 patent infringement under paragraph  
24 (6); and

1                   “(II) the list of patents, in ac-  
2 cordance with clause (ii), that the ref-  
3 erence product sponsor believes should  
4 be the subject of an action for patent  
5 infringement under paragraph (6).

6                   “(ii) NUMBER OF PATENTS LISTED BY  
7 REFERENCE PRODUCT SPONSOR.—

8                   “(I) IN GENERAL.—Subject to  
9 subclause (II), the number of patents  
10 listed by the reference product spon-  
11 sor under clause (i)(II) may not ex-  
12 ceed the number of patents listed by  
13 the subsection (k) applicant under  
14 clause (i)(I).

15                   “(II) EXCEPTION.—If a sub-  
16 section (k) applicant does not list any  
17 patent under clause (i)(I), the ref-  
18 erence product sponsor may list 1 pat-  
19 ent under clause (i)(II).

20                   “(6) IMMEDIATE PATENT INFRINGEMENT AC-  
21 TION.—

22                   “(A) ACTION IF AGREEMENT ON PATENT  
23 LIST.—If the subsection (k) applicant and the  
24 reference product sponsor agree on patents as  
25 described in paragraph (4), not later than 30

1 days after such agreement, the reference prod-  
2 uct sponsor shall bring an action for patent in-  
3 fringement with respect to each such patent.

4 “(B) ACTION IF NO AGREEMENT ON PAT-  
5 ENT LIST.—If the provisions of paragraph (5)  
6 apply to the parties as described in paragraph  
7 (4)(B), not later than 30 days after the ex-  
8 change of lists under paragraph (5)(B), the ref-  
9 erence product sponsor shall bring an action for  
10 patent infringement with respect to each patent  
11 that is included on such lists.

12 “(C) NOTIFICATION AND PUBLICATION OF  
13 COMPLAINT.—

14 “(i) NOTIFICATION TO SECRETARY.—  
15 Not later than 30 days after a complaint  
16 is served to a subsection (k) applicant in  
17 an action for patent infringement described  
18 under this paragraph, the subsection (k)  
19 applicant shall provide the Secretary with  
20 notice and a copy of such complaint.

21 “(ii) PUBLICATION BY SECRETARY.—  
22 The Secretary shall publish in the Federal  
23 Register notice of a complaint received  
24 under clause (i).



1           “(7) NEWLY ISSUED OR LICENSED PATENTS.—

2           In the case of a patent that—

3                   “(A) is issued to, or exclusively licensed by,  
4                   the reference product sponsor after the date  
5                   that the reference product sponsor provided the  
6                   list to the subsection (k) applicant under para-  
7                   graph (3)(A); and

8                   “(B) the reference product sponsor reason-  
9                   ably believes that, due to the issuance of such  
10                  patent, a claim of patent infringement could  
11                  reasonably be asserted by the reference product  
12                  sponsor if a person not licensed by the ref-  
13                  erence product sponsor engaged in the making,  
14                  using, offering to sell, selling, or importing into  
15                  the United States of the biological product that  
16                  is the subject of the subsection (k) application,  
17                  not later than 30 days after such issuance or licens-  
18                  ing, the reference product sponsor shall provide to  
19                  the subsection (k) applicant a supplement to the list  
20                  provided by the reference product sponsor under  
21                  paragraph (3)(A) that includes such patent, not  
22                  later than 30 days after such supplement is pro-  
23                  vided, the subsection (k) applicant shall provide a  
24                  statement to the reference product sponsor in ac-

1 cordance with paragraph (3)(B), and such patent  
2 shall be subject to paragraph (8).

3 “(8) NOTICE OF COMMERCIAL MARKETING AND  
4 PRELIMINARY INJUNCTION.—

5 “(A) NOTICE OF COMMERCIAL MAR-  
6 KETING.—The subsection (k) applicant shall  
7 provide notice to the reference product sponsor  
8 not later than 180 days before the date of the  
9 first commercial marketing of the biological  
10 product licensed under subsection (k).

11 “(B) PRELIMINARY INJUNCTION.—After  
12 receiving the notice under subparagraph (A)  
13 and before such date of the first commercial  
14 marketing of such biological product, the ref-  
15 erence product sponsor may seek a preliminary  
16 injunction prohibiting the subsection (k) appli-  
17 cant from engaging in the commercial manufac-  
18 ture or sale of such biological product until the  
19 court decides the issue of patent validity, en-  
20 forcement, and infringement with respect to any  
21 patent that is—

22 “(i) included in the list provided by  
23 the reference product sponsor under para-  
24 graph (3)(A) or in the list provided by the

1 subsection (k) applicant under paragraph  
2 (3)(B); and

3 “(ii) not included, as applicable, on—

4 “(I) the list of patents described  
5 in paragraph (4); or

6 “(II) the lists of patents de-  
7 scribed in paragraph (5)(B).

8 “(C) REASONABLE COOPERATION.—If the  
9 reference product sponsor has sought a prelimi-  
10 nary injunction under subparagraph (B), the  
11 reference product sponsor and the subsection  
12 (k) applicant shall reasonably cooperate to ex-  
13 pedite such further discovery as is needed in  
14 connection with the preliminary injunction mo-  
15 tion.

16 “(9) LIMITATION ON DECLARATORY JUDGMENT  
17 ACTION.—

18 “(A) SUBSECTION (k) APPLICATION PRO-  
19 VIDED.—If a subsection (k) applicant provides  
20 the application and information required under  
21 paragraph (2)(A), neither the reference product  
22 sponsor nor the subsection (k) applicant may,  
23 prior to the date notice is received under para-  
24 graph (8)(A), bring any action under section  
25 2201 of title 28, United States Code, for a dec-

1           laration of infringement, validity, or enforce-  
2           ability of any patent that is described in clauses  
3           (i) and (ii) of paragraph (8)(B).

4           “(B) SUBSEQUENT FAILURE TO ACT BY  
5           SUBSECTION (k) APPLICANT.—If a subsection  
6           (k) applicant fails to complete an action re-  
7           quired of the subsection (k) applicant under  
8           paragraph (3)(B)(ii), paragraph (5), paragraph  
9           (6)(C)(i), paragraph (7), or paragraph (8)(A),  
10          the reference product sponsor, but not the sub-  
11          section (k) applicant, may bring an action  
12          under section 2201 of title 28, United States  
13          Code, for a declaration of infringement, validity,  
14          or enforceability of any patent included in the  
15          list described in paragraph (3)(A), including as  
16          provided under paragraph (7).

17          “(C) SUBSECTION (k) APPLICATION NOT  
18          PROVIDED.—If a subsection (k) applicant fails  
19          to provide the application and information re-  
20          quired under paragraph (2)(A), the reference  
21          product sponsor, but not the subsection (k) ap-  
22          plicant, may bring an action under section 2201  
23          of title 28, United States Code, for a declara-  
24          tion of infringement, validity, or enforceability

1           of any patent that claims the biological product  
2           or a use of the biological product.”.

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

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

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

9           (2) in paragraph (1), as so designated, by in-  
10          serting “protein (except any chemically synthesized  
11          polypeptide),” after “allergenic product,”; and

12          (3) by adding at the end the following:

13          “(2) The term ‘biosimilar’ or ‘biosimilarity’, in  
14          reference to a biological product that is the subject  
15          of an application under subsection (k), means there  
16          are no clinically meaningful differences between the  
17          biological product and the reference product in  
18          terms of the safety, purity, and potency of the prod-  
19          uct.

20          “(3) The term ‘interchangeable’ or ‘inter-  
21          changeability’, in reference to a biological product  
22          that is the subject of an application under sub-  
23          section (k), means that the biological product may  
24          be substituted for the reference product without the

1 intervention of the health care provider who pre-  
2 scribed the reference product.

3 “(4) The term ‘reference product’ means the  
4 single biological product licensed under subsection  
5 (a) against which a biological product is evaluated in  
6 an application submitted under subsection (k).”.

7 (c) CONFORMING AMENDMENTS RELATING TO PAT-  
8 ENTS.—

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

11 (A) in paragraph (2)—

12 (i) in subparagraph (A), by striking  
13 “or” at the end;

14 (ii) in subparagraph (B), by adding  
15 “or” at the end; and

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

18 “(C)(i) with respect to a patent that is identi-  
19 fied in the list of patents described in section  
20 351(l)(3) of the Public Health Service Act (including  
21 as provided under section 351(l)(7) of such Act), an  
22 application seeking approval of a biological product,  
23 or

24 “(ii) if the applicant for the application fails to  
25 provide the application and information required

1 under section 351(l)(2)(A) of such Act, an applica-  
2 tion seeking approval of a biological product for a  
3 patent that could be identified pursuant to section  
4 351(l)(3)(A)(i) of such Act,”; and

5 (iv) in the matter following subpara-  
6 graph (C) (as added by clause (iii)), by  
7 striking “or veterinary biological product”  
8 and inserting “, veterinary biological prod-  
9 uct, or biological product”;

10 (B) in paragraph (4)—

11 (i) in subparagraph (B), by—

12 (I) striking “or veterinary bio-  
13 logical product” and inserting “, vet-  
14 erinary biological product, or biologi-  
15 cal product”; and

16 (II) striking “and” at the end;

17 (ii) in subparagraph (C), by—

18 (I) striking “or veterinary bio-  
19 logical product” and inserting “, vet-  
20 erinary biological product, or biologi-  
21 cal product”; and

22 (II) striking the period and in-  
23 serting “, and”;

24 (iii) by inserting after subparagraph  
25 (C) the following:

1           “(D) the court shall order a permanent injunc-  
2           tion prohibiting any infringement of the patent by  
3           the biological product involved in the infringement  
4           until a date which is not earlier than the date of the  
5           expiration of the patent that has been infringed  
6           under paragraph (2)(C), provided the patent is the  
7           subject of a final court decision, as defined in sec-  
8           tion 351(k)(6) of the Public Health Service Act, in  
9           an action for infringement of the patent under sec-  
10          tion 351(l)(6) of such Act, and the biological prod-  
11          uct has not yet been approved because of section  
12          351(k)(7) of such Act.”; and

13                       (iv) in the matter following subpara-  
14                       graph (D) (as added by clause (iii)), by  
15                       striking “and (C)” and inserting “(C), and  
16                       (D)”;

17                       (C) by adding at the end the following:

18          “(6)(A) Subparagraph (B) applies, in lieu of para-  
19          graph (4), in the case of a patent—

20                       “(i) that is identified, as applicable, in the list  
21                       of patents described in section 351(l)(4) of the Pub-  
22                       lic Health Service Act or the lists of patents de-  
23                       scribed in section 351(l)(5)(B) of such Act with re-  
24                       spect to a biological product; and



1           “(ii) for which an action for infringement of the  
2           patent with respect to the biological product—

3           “(I) was brought after the expiration of  
4           the 30-day period described in subparagraph  
5           (A) or (B), as applicable, of section 351(l)(6) of  
6           such Act; or

7           “(II) was brought before the expiration of  
8           the 30-day period described in subclause (I),  
9           but which was dismissed without prejudice or  
10          was not prosecuted to judgment in good faith.

11          “(B) In an action for infringement of a patent de-  
12          scribed in subparagraph (A), the sole and exclusive remedy  
13          that may be granted by a court, upon a finding that the  
14          making, using, offering to sell, selling, or importation into  
15          the United States of the biological product that is the sub-  
16          ject of the action infringed the patent, shall be a reason-  
17          able royalty.

18          “(C) The owner of a patent that should have been  
19          included in the list described in section 351(l)(3)(A) of  
20          the Public Health Service Act, including as provided under  
21          section 351(l)(7) of such Act for a biological product, but  
22          was not timely included in such list, may not bring an  
23          action under this section for infringement of the patent  
24          with respect to the biological product.”.

1           (2) CONFORMING AMENDMENT UNDER TITLE  
2           28.—Section 2201(b) of title 28, United States  
3           Code, is amended by inserting before the period the  
4           following: “, or section 351 of the Public Health  
5           Service Act”.

6           (d) CONFORMING AMENDMENTS UNDER THE FED-  
7           ERAL FOOD, DRUG, AND COSMETIC ACT.—

8           (1) CONTENT AND REVIEW OF APPLICA-  
9           TIONS.—Section 505(b)(5)(B) of the Federal Food,  
10          Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is  
11          amended by inserting before the period at the end  
12          of the first sentence the following: “or, with respect  
13          to an applicant for approval of a biological product  
14          under section 351(k) of the Public Health Service  
15          Act, any necessary clinical study or studies”.

16          (2) NEW ACTIVE INGREDIENT.—Section 505B  
17          of the Federal Food, Drug, and Cosmetic Act (21  
18          U.S.C. 355c) is amended by adding at the end the  
19          following:

20          “(i) NEW ACTIVE INGREDIENT.—A biological prod-  
21          uct that is interchangeable with a reference product under  
22          section 351 of the Public Health Service Act shall not be  
23          considered to have a new active ingredient under this sec-  
24          tion.”.

1 (e) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-  
2 TION 505.—

3 (1) REQUIREMENT TO FOLLOW SECTION 351.—

4 Except as provided in paragraph (2), an application  
5 for a biological product shall be submitted under  
6 section 351 of the Public Health Service Act (42  
7 U.S.C. 262) (as amended by this Act).

8 (2) EXCEPTION.—An application for a biologi-  
9 cal product may be submitted under section 505 of  
10 the Federal Food, Drug, and Cosmetic Act (21  
11 U.S.C. 355) if—

12 (A) such biological product is in a product  
13 class for which a biological product in such  
14 product class is the subject of an application  
15 approved under such section 505 not later than  
16 the date of enactment of this Act; and

17 (B) such application—

18 (i) has been submitted to the Sec-  
19 retary of Health and Human Services (re-  
20 ferred to in this Act as the “Secretary”)  
21 before the date of enactment of this Act;  
22 or

23 (ii) is submitted to the Secretary not  
24 later than the date that is 10 years after  
25 the date of enactment of this Act.

1           (3) LIMITATION.—Notwithstanding paragraph  
2           (2), an application for a biological product may not  
3           be submitted under section 505 of the Federal Food,  
4           Drug, and Cosmetic Act (21 U.S.C. 355) if there is  
5           another biological product approved under sub-  
6           section (a) of section 351 of the Public Health Serv-  
7           ice Act that could be a reference product with re-  
8           spect to such application (within the meaning of  
9           such section 351) if such application were submitted  
10          under subsection (k) of such section 351.

11          (4) DEEMED APPROVED UNDER SECTION  
12          351.—An approved application for a biological prod-  
13          uct under section 505 of the Federal Food, Drug,  
14          and Cosmetic Act (21 U.S.C. 355) shall be deemed  
15          to be a license for the biological product under such  
16          section 351 on the date that is 10 years after the  
17          date of enactment of this Act.

18          (5) DEFINITIONS.—For purposes of this sub-  
19          section, the term “biological product” has the mean-  
20          ing given such term under section 351 of the Public  
21          Health Service Act (42 U.S.C. 262) (as amended by  
22          this Act).

23          (f) FOLLOW-ON BIOLOGICS USER FEES.—

24                 (1) DEVELOPMENT OF USER FEES FOR BIO-  
25                 SIMILAR BIOLOGICAL PRODUCTS.—

1 (A) IN GENERAL.—Beginning not later  
2 than October 1, 2010, the Secretary shall de-  
3 velop recommendations to present to Congress  
4 with respect to the goals, and plans for meeting  
5 the goals, for the process for the review of bio-  
6 similar biological product applications sub-  
7 mitted under section 351(k) of the Public  
8 Health Service Act (as added by this Act) for  
9 the first 5 fiscal years after fiscal year 2012. In  
10 developing such recommendations, the Sec-  
11 retary shall consult with—

12 (i) the Committee on Health, Edu-  
13 cation, Labor, and Pensions of the Senate;

14 (ii) the Committee on Energy and  
15 Commerce of the House of Representa-  
16 tives;

17 (iii) scientific and academic experts;

18 (iv) health care professionals;

19 (v) representatives of patient and con-  
20 sumer advocacy groups; and

21 (vi) the regulated industry.

22 (B) PUBLIC REVIEW OF RECOMMENDA-  
23 TIONS.—After negotiations with the regulated  
24 industry, the Secretary shall—

1 (i) present the recommendations de-  
2 veloped under subparagraph (A) to the  
3 Congressional committees specified in such  
4 subparagraph;

5 (ii) publish such recommendations in  
6 the Federal Register;

7 (iii) provide for a period of 30 days  
8 for the public to provide written comments  
9 on such recommendations;

10 (iv) hold a meeting at which the pub-  
11 lic may present its views on such rec-  
12 ommendations; and

13 (v) after consideration of such public  
14 views and comments, revise such rec-  
15 ommendations as necessary.

16 (C) TRANSMITTAL OF RECOMMENDA-  
17 TIONS.—Not later than January 15, 2012, the  
18 Secretary shall transmit to Congress the revised  
19 recommendations under subparagraph (B), a  
20 summary of the views and comments received  
21 under such subparagraph, and any changes  
22 made to the recommendations in response to  
23 such views and comments.

24 (2) ESTABLISHMENT OF USER FEE PRO-  
25 GRAM.—It is the sense of the Senate that, based on

1 the recommendations transmitted to Congress by the  
2 Secretary pursuant to paragraph (1)(C), Congress  
3 should authorize a program, effective on October 1,  
4 2012, for the collection of user fees relating to the  
5 submission of biosimilar biological product applica-  
6 tions under section 351(k) of the Public Health  
7 Service Act (as added by this Act).

8 (3) TRANSITIONAL PROVISIONS FOR USER FEES  
9 FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

10 (A) APPLICATION OF THE PRESCRIPTION  
11 DRUG USER FEE PROVISIONS.—Section  
12 735(1)(C) of the Federal Food, Drug, and Cos-  
13 metic Act (21 U.S.C. 379g(1)(C)) is amended  
14 by striking “section 351” and inserting “sub-  
15 section (a) or (k) of section 351”.

16 (B) EVALUATION OF COSTS OF REVIEWING  
17 BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-  
18 TIONS.—During the period beginning on the  
19 date of enactment of this Act and ending on  
20 October 1, 2010, the Secretary shall collect and  
21 evaluate data regarding the costs of reviewing  
22 applications for biological products submitted  
23 under section 351(k) of the Public Health Serv-  
24 ice Act (as added by this Act) during such pe-  
25 riod.

1 (C) AUDIT.—

2 (i) IN GENERAL.—On the date that is  
3 2 years after first receiving a user fee ap-  
4 plicable to an application for a biological  
5 product under section 351(k) of the Public  
6 Health Service Act (as added by this Act),  
7 and on a biennial basis thereafter until Oc-  
8 tober 1, 2013, the Secretary shall perform  
9 an audit of the costs of reviewing such ap-  
10 plications under such section 351(k). Such  
11 an audit shall compare—

12 (I) the costs of reviewing such  
13 applications under such section  
14 351(k) to the amount of the user fee  
15 applicable to such applications; and

16 (II)(aa) such ratio determined  
17 under subclause (I); to

18 (bb) the ratio of the costs of re-  
19 viewing applications for biological  
20 products under section 351(a) of such  
21 Act (as amended by this Act) to the  
22 amount of the user fee applicable to  
23 such applications under such section  
24 351(a).



1                   (ii) ALTERATION OF USER FEE.—If  
2                   the audit performed under clause (i) indi-  
3                   cates that the ratios compared under sub-  
4                   clause (II) of such clause differ by more  
5                   than 5 percent, then the Secretary shall  
6                   alter the user fee applicable to applications  
7                   submitted under such section 351(k) to  
8                   more appropriately account for the costs of  
9                   reviewing such applications.

10                   (iii) ACCOUNTING STANDARDS.—The  
11                   Secretary shall perform an audit under  
12                   clause (i) in conformance with the account-  
13                   ing principles, standards, and requirements  
14                   prescribed by the Comptroller General of  
15                   the United States under section 3511 of  
16                   title 31, United State Code, to ensure the  
17                   validity of any potential variability.

18                   (4) AUTHORIZATION OF APPROPRIATIONS.—  
19                   There is authorized to be appropriated to carry out  
20                   this subsection such sums as may be necessary for  
21                   each of fiscal years 2008 through 2012.

22                   (g) ALLOCATION OF SAVINGS; SPECIAL RESERVE  
23                   FUND.—

24                   (1) DETERMINATION OF SAVINGS.—The Sec-  
25                   retary of the Treasury, in consultation with the Sec-

1       retary, shall for each fiscal year determine the  
2       amount of the savings to the Federal Government as  
3       a result of the enactment of this Act and shall trans-  
4       fer such amount to the Fund established under  
5       paragraph (2) pursuant to a relevant appropriations  
6       Act.

7               (2) SPECIAL RESERVE FUND.—

8                       (A) IN GENERAL.—There is established in  
9                       the Treasury of the United States a fund to be  
10                      designated as the “Biological Product Savings  
11                      Fund” to be made available to the Secretary  
12                      without fiscal year limitation.

13                     (B) USE OF FUND.—The amounts made  
14                     available to the Secretary through the Fund  
15                     under subparagraph (A) shall be expended on  
16                     activities authorized under the Public Health  
17                     Service Act.

18               (3) AUTHORIZATION OF APPROPRIATIONS.—

19       There is authorized to be appropriated for each fis-  
20       cal year to the Fund established under paragraph  
21       (2), the amount of the savings determined for such  
22       fiscal year under paragraph (1).