

**Calendar No. 1127**110<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION**S. 1695**

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**

JUNE 26, 2007

Mr. KENNEDY (for himself, Mr. HATCH, Mrs. CLINTON, Mr. ENZI, and Mr. SCHUMER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

NOVEMBER 19, 2008

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Biologics Price Com-  
3 petition and Innovation Act of 2007”.

4 **SEC. 2. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL**  
5 **PRODUCTS.**

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

9 (1) in subsection (a)(1)(A), by inserting “under  
10 this subsection or subsection (k)” after “biologics li-  
11 cense”; and

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

13 “(k) **LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-**  
14 **SIMILAR OR INTERCHANGEABLE.**—

15 “(1) **IN GENERAL.**—Any person may submit an  
16 application for licensure of a biological product  
17 under this subsection.

18 “(2) **CONTENT.**—

19 “(A) **IN GENERAL.**—

20 “(i) **REQUIRED INFORMATION.**—An  
21 application submitted under this subsection  
22 shall include information demonstrating  
23 that—

24 “(I) the biological product is bio-  
25 similar to a reference product based  
26 upon data derived from—

1           “(aa) analytical studies that  
2 demonstrate that the biological  
3 product is highly similar to the  
4 reference product notwith-  
5 standing minor differences in  
6 clinically inactive components;

7           “(bb) animal studies; and

8           “(cc) a clinical study or  
9 studies (including the assessment  
10 of immunogenicity and pharma-  
11 cokinetics or pharmacodynamics)  
12 that are—

13           “(AA) sufficient to  
14 demonstrate safety, purity,  
15 and potency in 1 or more  
16 appropriate conditions of use  
17 for which the reference  
18 product is licensed and in-  
19 tended to be used and for  
20 which licensure is sought for  
21 the biological product; and

22           “(BB) designed to  
23 avoid needlessly duplicative  
24 or unethical clinical testing;

1           “(II) the biological product and  
2           reference product utilize the same  
3           mechanism or mechanisms of action  
4           for the condition or conditions of use  
5           prescribed, recommended, or sug-  
6           gested in the proposed labeling, but  
7           only to the extent the mechanism or  
8           mechanisms of action are known for  
9           the reference product;

10           “(III) the condition or conditions  
11           of use prescribed, recommended, or  
12           suggested in the labeling proposed for  
13           the biological product have been pre-  
14           viously approved for the reference  
15           product;

16           “(IV) the route of administra-  
17           tion, the dosage form, and the  
18           strength of the biological product are  
19           the same as those of the reference  
20           product; and

21           “(V) the facility in which the bio-  
22           logical product is manufactured, proc-  
23           essed, packed, or held meets stand-  
24           ards designed to assure that the bio-

1                   logical product continues to be safe,  
2                   pure, and potent.

3                   “(ii) DETERMINATION BY SEC-  
4                   RETARY.—The Secretary may determine,  
5                   in the Secretary’s discretion, that an ele-  
6                   ment described in clause (i)(I) is unneces-  
7                   sary in an application submitted under this  
8                   subsection.

9                   “(iii) ADDITIONAL INFORMATION.—  
10                  An application submitted under this sub-  
11                  section may include—

12                   “(I) at the applicant’s option,  
13                   publicly-available information regard-  
14                   ing the Secretary’s previous deter-  
15                   mination that the reference product is  
16                   safe, pure, and potent; and

17                   “(II) any additional information  
18                   in support of the application, includ-  
19                   ing publicly-available information with  
20                   respect to the reference product or an-  
21                   other biological product.

22                   “(B) INTERCHANGEABILITY.—An applica-  
23                   tion (or a supplement to an application) sub-  
24                   mitted under this subsection may include infor-  
25                   mation demonstrating that the biological prod-

1           uct is interchangeable with the reference prod-  
2           uct.

3           “(3) EVALUATION BY SECRETARY.—Upon re-  
4           view of an application (or a supplement to an appli-  
5           cation) submitted under this subsection, the Sec-  
6           retary shall license the biological product under this  
7           subsection if the Secretary determines that the infor-  
8           mation submitted in the application (or the suppl-  
9           ment) is sufficient to show that the biological prod-  
10          uct—

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

12           or

13                   “(B) is interchangeable with the reference  
14           product.

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

24                   “(A) the biological product—

1           “(i) is biosimilar to the reference  
2           product; and

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

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

13          “(5) GENERAL RULES.—

14           “(A) ONE REFERENCE PRODUCT PER AP-  
15           PLICATION.—A biological product, in an appli-  
16           cation submitted under this subsection, may not  
17           be evaluated against more than 1 reference  
18           product.

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

1           “(C) RISK EVALUATION AND MITIGATION  
2 STRATEGIES.—The authority of the Secretary  
3 with respect to risk evaluation and mitigation  
4 strategies under the Federal Food, Drug, and  
5 Cosmetic Act shall apply to biological products  
6 licensed under this subsection in the same man-  
7 ner as such authority applies to biological prod-  
8 ucts licensed under subsection (a).

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

19           “(A) 1 year after the first commercial  
20 marketing of the first interchangeable bio-  
21 similar biological product to be approved as  
22 interchangeable for that reference product;

23           “(B) 18 months after—

24           “(i) a final court decision on all pat-  
25 ents in suit in an action instituted under



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

5 “(ii) the dismissal with or without  
6 prejudice of an action instituted under sub-  
7 section (1)(6) against the applicant that  
8 submitted the application for the first ap-  
9 proved interchangeable biosimilar biological  
10 product; or

11 “(C)(i) 42 months after approval of the  
12 first interchangeable biosimilar biological prod-  
13 uct if the applicant that submitted such appli-  
14 cation has been sued under subsection (1)(6)  
15 and such litigation is still ongoing within such  
16 36-month period; or

17 “(ii) 18 months after approval of the first  
18 interchangeable biosimilar biological product if  
19 the applicant that submitted such application  
20 has not been sued under subsection (1)(6).

21 For purposes of this paragraph, the term ‘final court  
22 decision’ means a final decision of a court from  
23 which no appeal (other than a petition to the United  
24 States Supreme Court for a writ of certiorari) has  
25 been or can be taken.

1           ~~“(7) EXCLUSIVITY FOR REFERENCE PROD-~~  
2           ~~UCT.—~~

3           ~~“(A) EFFECTIVE DATE OF BIOSIMILAR AP-~~  
4           ~~PLICATION APPROVAL.—~~Approval of an applica-  
5           tion under this subsection may not be made ef-  
6           fective by the Secretary until the date that is  
7           ~~12~~ years after the date on which the reference  
8           product was first licensed under subsection (a).

9           ~~“(B) FILING PERIOD.—~~An application  
10           under this subsection may not be submitted to  
11           the Secretary until the date that is 4 years  
12           after the date on which the reference product  
13           was first licensed under subsection (a).

14           ~~“(8) GUIDANCE DOCUMENTS.—~~

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

24           ~~“(B) PUBLIC COMMENT.—~~

1           “(i) IN GENERAL.—The Secretary  
2           shall provide the public an opportunity to  
3           comment on any proposed guidance issued  
4           under subparagraph (A) before issuing  
5           final guidance.

6           “(ii) INPUT REGARDING MOST VALU-  
7           ABLE GUIDANCE.—The Secretary shall es-  
8           tablish a process through which the public  
9           may provide the Secretary with input re-  
10          garding priorities for issuing guidance.

11          “(C) NO REQUIREMENT FOR APPLICATION  
12          CONSIDERATION.—The issuance (or non-  
13          issuance) of guidance under subparagraph (A)  
14          shall not preclude the review of, or action on,  
15          an application submitted under this subsection.

16          “(D) REQUIREMENT FOR PRODUCT CLASS-  
17          SPECIFIC GUIDANCE.—If the Secretary issues  
18          product class-specific guidance under subpara-  
19          graph (A), such guidance shall include a de-  
20          scription of—

21                 “(i) the criteria that the Secretary will  
22                 use to determine whether a biological prod-  
23                 uct is highly similar to a reference product  
24                 in such product class; and

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

5           “(E) CERTAIN PRODUCT CLASSES.—

6           “(i) GUIDANCE.—The Secretary may  
7 indicate in a guidance document that the  
8 science and experience, as of the date of  
9 such guidance, with respect to a product or  
10 product class (not including any recom-  
11 binant protein) does not allow approval of  
12 an application for a license as provided  
13 under this subsection for such product or  
14 product class.

15           “(ii) MODIFICATION OR REVERSAL.—

16 The Secretary may issue a subsequent  
17 guidance document under subparagraph  
18 (A) to modify or reverse a guidance docu-  
19 ment under clause (i).

20           “(iii) NO EFFECT ON ABILITY TO  
21 DENY LICENSE.—Clause (i) shall not be  
22 construed to require the Secretary to ap-  
23 prove a product with respect to which the  
24 Secretary has not indicated in a guidance  
25 document that the science and experience,

1 as described in clause (i), does not allow  
2 approval of such an application.

3 “(1) PATENTS.—

4 “(1) CONFIDENTIAL ACCESS TO SUBSECTION  
5 (k) APPLICATION.—

6 “(A) APPLICATION OF PARAGRAPH.—Un-  
7 less otherwise agreed to by a person that sub-  
8 mits an application under subsection (k) (re-  
9 ferred to in this subsection as the ‘subsection  
10 (k) applicant’) and the sponsor of the applica-  
11 tion for the reference product (referred to in  
12 this paragraph as the ‘reference product spon-  
13 sor’), the provisions of this paragraph shall  
14 apply to the exchange of information described  
15 in this subsection.

16 “(B) IN GENERAL.—

17 “(i) PROVISION OF CONFIDENTIAL IN-  
18 FORMATION.—When a subsection (k) ap-  
19 plicant submits an application under sub-  
20 section (k), such applicant shall provide to  
21 the persons described in clause (ii), subject  
22 to the terms of this paragraph, confidential  
23 access to the information required to be  
24 produced pursuant to paragraph (2) and  
25 any other information that the subsection

1 (k) applicant determines, in its sole discre-  
2 tion, to be appropriate (referred to in this  
3 subsection as the ‘confidential informa-  
4 tion’).

5 “(ii) RECIPIENTS OF INFORMATION.—

6 The persons described in this clause are  
7 the following:

8 “(I) OUTSIDE COUNSEL.—One or

9 more attorneys designated by the ref-  
10 erence product sponsor who are em-  
11 ployees of an entity other than the  
12 reference product sponsor (referred to  
13 in this paragraph as the ‘outside  
14 counsel’), provided that such attor-  
15 neys do not engage, formally or infor-  
16 mally, in patent prosecution relevant  
17 or related to the reference product.

18 “(II) IN-HOUSE COUNSEL.—One

19 attorney that represents the reference  
20 product sponsor who is an employee  
21 of the reference product sponsor, pro-  
22 vided that such attorney does not en-  
23 gage, formally or informally, in patent  
24 prosecution relevant or related to the  
25 reference product.

1           “(C) LIMITATION ON DISCLOSURE.—No  
2 person that receives confidential information  
3 pursuant to subparagraph (B) shall disclose  
4 any confidential information to any other per-  
5 son or entity, including the reference product  
6 sponsor employees, outside scientific consult-  
7 ants, or other outside counsel retained by the  
8 reference product sponsor, without the prior  
9 written consent of the subsection (k) applicant,  
10 which shall not be unreasonably withheld.

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

23           “(E) OWNERSHIP OF CONFIDENTIAL IN-  
24 FORMATION.—The confidential information dis-  
25 closed under this paragraph is, and shall re-

1 main, the property of the subsection (k) appli-  
2 cant. By providing the confidential information  
3 pursuant to this paragraph, the subsection (k)  
4 applicant does not provide the reference product  
5 sponsor or the outside counsel any interest in or  
6 license to use the confidential information, for  
7 purposes other than those specified in subpara-  
8 graph (D).

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



1           vided that if the reference product sponsor opts  
2           to destroy such information, it will confirm de-  
3           struction in writing to the subsection (k) appli-  
4           cant.

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

7                   “(i) as an admission by the subsection  
8                   (k) applicant regarding the validity, en-  
9                   forceability, or infringement of any patent;  
10                  or

11                  “(ii) an agreement or admission by  
12                  the subsection (k) applicant with respect to  
13                  the competency, relevance, or materiality  
14                  of any confidential information.

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

24           “(2) SUBSECTION (k) APPLICATION INFORMA-  
25           TION.—Not later than 20 days after the Secretary

1 notifies the subsection (k) applicant that the applica-  
2 tion has been accepted for review, the subsection (k)  
3 applicant—

4 “(A) shall provide to the reference product  
5 sponsor a copy of the application submitted to  
6 the Secretary under subsection (k), and such  
7 other information that describes the process or  
8 processes used to manufacture the biological  
9 product that is the subject of such application;  
10 and

11 “(B) may provide to the reference product  
12 sponsor additional information requested by or  
13 on behalf of the reference product sponsor.

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

15 “(A) LIST BY REFERENCE PRODUCT SPON-  
16 SOR.—Not later than 60 days after the receipt  
17 of the application and information under para-  
18 graph (2), the reference product sponsor shall  
19 provide to the subsection (k) applicant—

20 “(i) a list of patents for which the ref-  
21 erence product sponsor believes a claim of  
22 patent infringement could reasonably be  
23 asserted by the reference product sponsor  
24 if a person not licensed by the reference  
25 product sponsor engaged in the making;

1 using, offering to sell, selling, or importing  
2 into the United States of the biological  
3 product that is the subject of the sub-  
4 section (k) application; and

5 “(ii) an identification of the patents  
6 on such list that the reference product  
7 sponsor would be prepared to license to the  
8 subsection (k) applicant.

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

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

24 “(ii) shall provide to the reference  
25 product sponsor, with respect to each pat-

1 ent listed by the reference product sponsor  
2 under subparagraph (A) or listed by the  
3 subsection (k) applicant under clause (i)—

4 “(I) a detailed statement that de-  
5 scribes, on a claim by claim basis, the  
6 factual and legal basis of the opinion  
7 of the subsection (k) applicant that  
8 such patent is invalid, unenforceable,  
9 or will not be infringed by the com-  
10 mercial marketing of the biological  
11 product that is the subject of the sub-  
12 section (k) application; or

13 “(II) a statement that the sub-  
14 section (k) applicant does not intend  
15 to begin commercial marketing of the  
16 biological product before the date that  
17 such patent expires; and

18 “(iii) shall provide to the reference  
19 product sponsor a response regarding each  
20 patent identified by the reference product  
21 sponsor under subparagraph (A)(ii).

22 “(C) DESCRIPTION BY REFERENCE PROD-  
23 UCT SPONSOR.—Not later than 60 days after  
24 receipt of the list and statement under subpara-  
25 graph (B), the reference product sponsor shall

1 provide to the subsection (k) applicant a de-  
2 tailed statement that describes, with respect to  
3 each patent described in subparagraph  
4 (B)(ii)(I), on a claim by claim basis, the factual  
5 and legal basis of the opinion of the reference  
6 product sponsor that such patent will be in-  
7 fringed by the commercial marketing of the bio-  
8 logical product that is the subject of the sub-  
9 section (k) application and a response to the  
10 statement concerning validity and enforceability  
11 provided under subparagraph (B)(ii)(I).

12 “(4) PATENT RESOLUTION NEGOTIATIONS.—

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

23 “(B) FAILURE TO REACH AGREEMENT.—  
24 If, within 15 days of beginning negotiations  
25 under subparagraph (A), the subsection (k) ap-

1           plicant and the reference product sponsor fail to  
2           agree on a final and complete list of which, if  
3           any, patents listed under paragraph (3) by the  
4           subsection (k) applicant or the reference prod-  
5           uct sponsor shall be the subject of an action for  
6           patent infringement under paragraph (6); the  
7           provisions of paragraph (5) shall apply to the  
8           parties.

9           “(5) PATENT RESOLUTION IF NO AGREE-  
10          MENT.—

11           “(A) NUMBER OF PATENTS.—The sub-  
12           section (k) applicant shall notify the reference  
13           product sponsor of the number of patents that  
14           such applicant will provide to the reference  
15           product sponsor under subparagraph (B)(i)(I).

16           “(B) EXCHANGE OF PATENT LISTS.—

17           “(i) IN GENERAL.—On a date agreed  
18           to by the subsection (k) applicant and the  
19           reference product sponsor, but in no case  
20           later than 5 days after the subsection (k)  
21           application notifies the reference product  
22           sponsor under subparagraph (A); the sub-  
23           section (k) applicant and the reference  
24           product sponsor shall simultaneously ex-  
25           change—

1           “(I) the list of patents that the  
2           subsection (k) applicant believes  
3           should be the subject of an action for  
4           patent infringement under paragraph  
5           (6); and

6           “(II) the list of patents, in ac-  
7           cordance with clause (ii), that the ref-  
8           erence product sponsor believes should  
9           be the subject of an action for patent  
10          infringement under paragraph (6).

11          “(ii) NUMBER OF PATENTS LISTED BY  
12          REFERENCE PRODUCT SPONSOR.—

13           “(I) IN GENERAL.—Subject to  
14           subclause (II), the number of patents  
15           listed by the reference product spon-  
16           sor under clause (i)(II) may not ex-  
17           ceed the number of patents listed by  
18           the subsection (k) applicant under  
19           clause (i)(I).

20           “(II) EXCEPTION.—If a sub-  
21           section (k) applicant does not list any  
22           patent under clause (i)(I), the ref-  
23           erence product sponsor may list 1 pat-  
24           ent under clause (i)(II).

1           “(6) IMMEDIATE PATENT INFRINGEMENT AC-  
2           TION.—

3           “(A) ACTION IF AGREEMENT ON PATENT  
4           LIST.—If the subsection (k) applicant and the  
5           reference product sponsor agree on patents as  
6           described in paragraph (4), not later than 30  
7           days after such agreement, the reference prod-  
8           uct sponsor shall bring an action for patent in-  
9           fringement with respect to each such patent.

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

18          “(C) NOTIFICATION AND PUBLICATION OF  
19          COMPLAINT.—

20          “(i) NOTIFICATION TO SECRETARY.—  
21          Not later than 30 days after a complaint  
22          is served to a subsection (k) applicant in  
23          an action for patent infringement described  
24          under this paragraph, the subsection (k)



1 applicant shall provide the Secretary with  
2 notice and a copy of such complaint.

3 “(ii) PUBLICATION BY SECRETARY.—

4 The Secretary shall publish in the Federal  
5 Register notice of a complaint received  
6 under clause (i).

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

8 In the case of a patent that—

9 “(A) is issued to, or exclusively licensed by,  
10 the reference product sponsor after the date  
11 that the reference product sponsor provided the  
12 list to the subsection (k) applicant under para-  
13 graph (3)(A); and

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

1 provided by the reference product sponsor under  
2 paragraph (3)(A) that includes such patent, not  
3 later than 30 days after such supplement is pro-  
4 vided, the subsection (k) applicant shall provide a  
5 statement to the reference product sponsor in ac-  
6 cordance with paragraph (3)(B), and such patent  
7 shall be subject to paragraph (8).

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

10 “(A) NOTICE OF COMMERCIAL MAR-  
11 KETING.—The subsection (k) applicant shall  
12 provide notice to the reference product sponsor  
13 not later than 180 days before the date of the  
14 first commercial marketing of the biological  
15 product licensed under subsection (k).

16 “(B) PRELIMINARY INJUNCTION.—After  
17 receiving the notice under subparagraph (A)  
18 and before such date of the first commercial  
19 marketing of such biological product, the ref-  
20 erence product sponsor may seek a preliminary  
21 injunction prohibiting the subsection (k) appli-  
22 cant from engaging in the commercial manufac-  
23 ture or sale of such biological product until the  
24 court decides the issue of patent validity, en-

1           forcement, and infringement with respect to any  
2           patent that is—

3                   “(i) included in the list provided by  
4                   the reference product sponsor under para-  
5                   graph (3)(A) or in the list provided by the  
6                   subsection (k) applicant under paragraph  
7                   (3)(B); and

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

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

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

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

21                   “(9) LIMITATION ON DECLARATORY JUDGMENT  
22                   ACTION.—

23                           “(A) SUBSECTION (k) APPLICATION PRO-  
24                           VIDED.—If a subsection (k) applicant provides  
25                           the application and information required under

1 paragraph (2)(A), neither the reference product  
2 sponsor nor the subsection (k) applicant may,  
3 prior to the date notice is received under para-  
4 graph (8)(A), bring any action under section  
5 2201 of title 28, United States Code, for a dec-  
6 laration of infringement, validity, or enforce-  
7 ability of any patent that is described in clauses  
8 (i) and (ii) of paragraph (8)(B).

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

22 “(C) SUBSECTION (k) APPLICATION NOT  
23 PROVIDED.—If a subsection (k) applicant fails  
24 to provide the application and information re-  
25 quired under paragraph (2)(A), the reference

1 product sponsor, but not the subsection (k) ap-  
2 plicant, may bring an action under section 2201  
3 of title 28, United States Code, for a declara-  
4 tion of infringement, validity, or enforceability  
5 of any patent that claims the biological product  
6 or a use of the biological product.”.

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

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

11 “In this section:

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

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

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

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

24 “(3) The term ‘interchangeable’ or ‘inter-  
25 changeability’, in reference to a biological product

1 that is the subject of an application under sub-  
 2 section (k), means that the biological product may  
 3 be substituted for the reference product without the  
 4 intervention of the health care provider who pre-  
 5 scribed the reference product.

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

10 (e) CONFORMING AMENDMENTS RELATING TO PAT-  
 11 ENTS.—

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

14 (A) in paragraph (2)—

15 (i) in subparagraph (A), by striking

16 “or” at the end;

17 (ii) in subparagraph (B), by adding

18 “or” at the end; and

19 (iii) by inserting after subparagraph

20 (B) the following:

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

1 application seeking approval of a biological product,  
2 or

3 “(ii) if the applicant for the application fails to  
4 provide the application and information required  
5 under section 351(1)(2)(A) of such Act, an applica-  
6 tion seeking approval of a biological product for a  
7 patent that could be identified pursuant to section  
8 351(1)(3)(A)(i) of such Act,”; and

9 (iv) in the matter following subpara-  
10 graph (C) (as added by clause (iii)), by  
11 striking “or veterinary biological product”  
12 and inserting “, veterinary biological prod-  
13 uct, or biological product”;

14 (B) in paragraph (4)—

15 (i) in subparagraph (B), by—

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

20 (II) striking “and” at the end;

21 (ii) in subparagraph (C), by—

22 (I) striking “or veterinary bio-  
23 logical product” and inserting “, vet-  
24 erinary biological product, or biologi-  
25 cal product”; and

1                   (H) striking the period and in-  
2                   serting “; and”;

3                   (iii) by inserting after subparagraph  
4                   (C) the following:

5                   “(D) the court shall order a permanent injune-  
6                   tion prohibiting any infringement of the patent by  
7                   the biological product involved in the infringement  
8                   until a date which is not earlier than the date of the  
9                   expiration of the patent that has been infringed  
10                  under paragraph (2)(C), provided the patent is the  
11                  subject of a final court decision, as defined in sec-  
12                  tion 351(k)(6) of the Public Health Service Act, in  
13                  an action for infringement of the patent under sec-  
14                  tion 351(l)(6) of such Act, and the biological prod-  
15                  uct has not yet been approved because of section  
16                  351(k)(7) of such Act.”; and

17                  (iv) in the matter following subpara-  
18                  graph (D) (as added by clause (iii)), by  
19                  striking “and (C)” and inserting “(C), and  
20                  (D)”;

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

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

24                  “(i) that is identified, as applicable, in the list  
25                  of patents described in section 351(l)(4) of the Pub-



1        lie Health Service Act or the lists of patents de-  
2        scribed in section 351(1)(5)(B) of such Act with re-  
3        spect to a biological product; and

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

6            “(I) was brought after the expiration of  
7        the 30-day period described in subparagraph  
8        (A) or (B), as applicable, of section 351(1)(6) of  
9        such Act; or

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

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

21           “(C) The owner of a patent that should have been  
22        included in the list described in section 351(1)(3)(A) of  
23        the Public Health Service Act, including as provided under  
24        section 351(1)(7) of such Act for a biological product, but  
25        was not timely included in such list, may not bring an

1 action under this section for infringement of the patent  
2 with respect to the biological product.”.

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

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

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

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

22           “(i) NEW ACTIVE INGREDIENT.—A biological prod-  
23 uct that is interchangeable with a reference product under  
24 section 351 of the Public Health Service Act shall not be

1 considered to have a new active ingredient under this sec-  
2 tion.”.

3 (c) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-  
4 TION 505.—

5 (1) REQUIREMENT TO FOLLOW SECTION 351.—

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

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

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

19 (B) such application—

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

24 or

1 (ii) is submitted to the Secretary not  
2 later than the date that is 10 years after  
3 the date of enactment of this Act.

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

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

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

1        ~~(f) FOLLOW-ON BIOLOGICS USER FEES.—~~

2                ~~(1) DEVELOPMENT OF USER FEES FOR BIO-~~  
3        ~~SIMILAR BIOLOGICAL PRODUCTS.—~~

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

15                ~~(i) the Committee on Health, Edu-~~  
16                ~~cation, Labor, and Pensions of the Senate;~~

17                ~~(ii) the Committee on Energy and~~  
18                ~~Commerce of the House of Representa-~~  
19                ~~tives;~~

20                ~~(iii) scientific and academic experts;~~

21                ~~(iv) health care professionals;~~

22                ~~(v) representatives of patient and con-~~  
23                ~~sumer advocacy groups; and~~

24                ~~(vi) the regulated industry.~~

1           (B) PUBLIC REVIEW OF RECOMMENDA-  
2 TIONS.—After negotiations with the regulated  
3 industry, the Secretary shall—

4           (i) present the recommendations de-  
5 veloped under subparagraph (A) to the  
6 Congressional committees specified in such  
7 subparagraph;

8           (ii) publish such recommendations in  
9 the Federal Register;

10          (iii) provide for a period of 30 days  
11 for the public to provide written comments  
12 on such recommendations;

13          (iv) hold a meeting at which the pub-  
14 lic may present its views on such rec-  
15 ommendations; and

16          (v) after consideration of such public  
17 views and comments, revise such rec-  
18 ommendations as necessary.

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

1           made to the recommendations in response to  
2           such views and comments.

3           ~~(2) ESTABLISHMENT OF USER FEE PRO-~~  
4           GRAM.—It is the sense of the Senate that, based on  
5           the recommendations transmitted to Congress by the  
6           Secretary pursuant to paragraph (1)(C), Congress  
7           should authorize a program, effective on October 1,  
8           2012, for the collection of user fees relating to the  
9           submission of biosimilar biological product applica-  
10          tions under section 351(k) of the Public Health  
11          Service Act (as added by this Act).

12          ~~(3) TRANSITIONAL PROVISIONS FOR USER FEES~~  
13          FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

14                 (A) APPLICATION OF THE PRESCRIPTION  
15                 DRUG USER FEE PROVISIONS.—Section  
16                 735(1)(C) of the Federal Food, Drug, and Cos-  
17                 metic Act (21 U.S.C. 379g(1)(C)) is amended  
18                 by striking “section 351” and inserting “sub-  
19                 section (a) or (k) of section 351”.

20                 (B) EVALUATION OF COSTS OF REVIEWING  
21                 BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-  
22                 TIONS.—During the period beginning on the  
23                 date of enactment of this Act and ending on  
24                 October 1, 2010, the Secretary shall collect and  
25                 evaluate data regarding the costs of reviewing

1 applications for biological products submitted  
2 under section 351(k) of the Public Health Serv-  
3 ice Act (as added by this Act) during such pe-  
4 riod.

5 (C) AUDIT.—

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

16 (I) the costs of reviewing such  
17 applications under such section  
18 351(k) to the amount of the user fee  
19 applicable to such applications; and

20 (II)(aa) such ratio determined  
21 under subclause (I); to

22 (bb) the ratio of the costs of re-  
23 viewing applications for biological  
24 products under section 351(a) of such  
25 Act (as amended by this Act) to the



1 amount of the user fee applicable to  
2 such applications under such section  
3 351(a).

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

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

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

1       (g) ALLOCATION OF SAVINGS; SPECIAL RESERVE  
2 FUND.—

3           (1) DETERMINATION OF SAVINGS.—The Sec-  
4 retary of the Treasury, in consultation with the Sec-  
5 retary, shall for each fiscal year determine the  
6 amount of the savings to the Federal Government as  
7 a result of the enactment of this Act and shall trans-  
8 fer such amount to the Fund established under  
9 paragraph (2) pursuant to a relevant appropriations  
10 Act.

11           (2) SPECIAL RESERVE FUND.—

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

17           (B) USE OF FUND.—The amounts made  
18 available to the Secretary through the Fund  
19 under subparagraph (A) shall be expended on  
20 activities authorized under the Public Health  
21 Service Act.

22           (3) AUTHORIZATION OF APPROPRIATIONS.—  
23 There is authorized to be appropriated for each fis-  
24 cal year to the Fund established under paragraph

1       (2), the amount of the savings determined for such  
2       fiscal year under paragraph (1).

3       **SECTION 1. SHORT TITLE.**

4       *This Act may be cited as the “Biologics Price Competi-*  
5       *tion and Innovation Act of 2007”.*

6       **SEC. 2. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL**  
7       **PRODUCTS.**

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

11               (1) *in subsection (a)(1)(A), by inserting “under*  
12       *this subsection or subsection (k)” after “biologics li-*  
13       *cence”; and*

14               (2) *by adding at the end the following:*

15       “(k) *LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-*  
16       *SIMILAR OR INTERCHANGEABLE.*—

17               “(1) *IN GENERAL.*—*Any person may submit an*  
18       *application for licensure of a biological product under*  
19       *this subsection.*

20               “(2) *CONTENT.*—

21                       “(A) *IN GENERAL.*—

22                               “(i) *REQUIRED INFORMATION.*—*An ap-*  
23       *plication submitted under this subsection*  
24       *shall include information demonstrating*  
25       *that—*

1           “(I) the biological product is bio-  
2 similar to a reference product based  
3 upon data derived from—

4           “(aa) analytical studies that  
5 demonstrate that the biological  
6 product is highly similar to the  
7 reference product notwithstanding  
8 minor differences in clinically in-  
9 active components;

10          “(bb) animal studies (includ-  
11 ing the assessment of toxicity);  
12 and

13          “(cc) a clinical study or  
14 studies (including the assessment  
15 of immunogenicity and phar-  
16 macokinetics or pharmaco-  
17 dynamics) that are sufficient to  
18 demonstrate safety, purity, and  
19 potency in 1 or more appropriate  
20 conditions of use for which the ref-  
21 erence product is licensed and in-  
22 tended to be used and for which  
23 licensure is sought for the biologi-  
24 cal product;

1           “(II) the biological product and  
2           reference product utilize the same  
3           mechanism or mechanisms of action  
4           for the condition or conditions of use  
5           prescribed, recommended, or suggested  
6           in the proposed labeling, but only to  
7           the extent the mechanism or mecha-  
8           nisms of action are known for the ref-  
9           erence product;

10           “(III) the condition or conditions  
11           of use prescribed, recommended, or sug-  
12           gested in the labeling proposed for the  
13           biological product have been previously  
14           approved for the reference product;

15           “(IV) the route of administration,  
16           the dosage form, and the strength of the  
17           biological product are the same as  
18           those of the reference product; and

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

1                   “(ii) *DETERMINATION BY SEC-*  
2                   *RETARY.—The Secretary may determine, in*  
3                   *the Secretary’s discretion, that an element*  
4                   *described in clause (i)(I) is unnecessary in*  
5                   *an application submitted under this sub-*  
6                   *section.*

7                   “(iii) *ADDITIONAL INFORMATION.—An*  
8                   *application submitted under this sub-*  
9                   *section—*

10                    “(I) *shall include publicly-avail-*  
11                    *able information regarding the Sec-*  
12                    *retary’s previous determination that*  
13                    *the reference product is safe, pure, and*  
14                    *potent; and*

15                    “(II) *may include any additional*  
16                    *information in support of the applica-*  
17                    *tion, including publicly-available in-*  
18                    *formation with respect to the reference*  
19                    *product or another biological product.*

20                   “(B) *INTERCHANGEABILITY.—An applica-*  
21                    *tion (or a supplement to an application) sub-*  
22                    *mitted under this subsection may include infor-*  
23                    *mation demonstrating that the biological product*  
24                    *meets the standards described in paragraph (4).*

1           “(3) *EVALUATION BY SECRETARY.*—Upon review  
2 of an application (or a supplement to an application)  
3 submitted under this subsection, the Secretary shall  
4 license the biological product under this subsection  
5 if—

6           “(A) the Secretary determines that the in-  
7 formation submitted in the application (or the  
8 supplement) is sufficient to show that the biologi-  
9 cal product—

10           “(i) is biosimilar to the reference prod-  
11 uct; or

12           “(ii) meets the standards described in  
13 paragraph (4), and therefore is interchange-  
14 able with the reference product; and

15           “(B) the applicant (or other appropriate  
16 person) consents to the inspection of the facility  
17 that is the subject of the application, in accord-  
18 ance with subsection (c).

19           “(4) *SAFETY STANDARDS FOR DETERMINING*  
20 *INTERCHANGEABILITY.*—Upon review of an applica-  
21 tion submitted under this subsection or any supple-  
22 ment to such application, the Secretary shall deter-  
23 mine the biological product to be interchangeable with  
24 the reference product if the Secretary determines that  
25 the information submitted in the application (or a

1       *supplement to such application) is sufficient to show*  
2       *that—*

3               “(A) *the biological product—*

4                       “(i) *is biosimilar to the reference prod-*  
5                       *uct; and*

6                       “(ii) *can be expected to produce the*  
7                       *same clinical result as the reference product*  
8                       *in any given patient; and*

9               “(B) *for a biological product that is admin-*  
10               *istered more than once to an individual, the risk*  
11               *in terms of safety or diminished efficacy of alter-*  
12               *nating or switching between use of the biological*  
13               *product and the reference product is not greater*  
14               *than the risk of using the reference product with-*  
15               *out such alternation or switch.*

16               “(5) *GENERAL RULES.—*

17                       “(A) *ONE REFERENCE PRODUCT PER APPLI-*  
18                       *CATION.—A biological product, in an applica-*  
19                       *tion submitted under this subsection, may not be*  
20                       *evaluated against more than 1 reference product.*

21                       “(B) *REVIEW.—An application submitted*  
22                       *under this subsection shall be reviewed by the di-*  
23                       *vision within the Food and Drug Administra-*  
24                       *tion that is responsible for the review and ap-*



1           *proval of the application under which the ref-*  
2           *erence product is licensed.*

3           “(C) *RISK EVALUATION AND MITIGATION*  
4           *STRATEGIES.—The authority of the Secretary*  
5           *with respect to risk evaluation and mitigation*  
6           *strategies under the Federal Food, Drug, and*  
7           *Cosmetic Act shall apply to biological products*  
8           *licensed under this subsection in the same man-*  
9           *ner as such authority applies to biological prod-*  
10          *ucts licensed under subsection (a).*

11          “(6) *EXCLUSIVITY FOR FIRST INTERCHANGEABLE*  
12          *BIOLOGICAL PRODUCT.—Upon review of an applica-*  
13          *tion submitted under this subsection relying on the*  
14          *same reference product for which a prior biological*  
15          *product has received a determination of interchange-*  
16          *ability for any condition of use, the Secretary shall*  
17          *not make a determination under paragraph (4) that*  
18          *the second or subsequent biological product is inter-*  
19          *changeable for any condition of use until the earlier*  
20          *of—*

21                 “(A) *1 year after the first commercial mar-*  
22                 *keting of the first interchangeable biosimilar bio-*  
23                 *logical product to be approved as interchangeable*  
24                 *for that reference product;*

25                 “(B) *18 months after—*

1           “(i) a final court decision on all pat-  
2           ents in suit in an action instituted under  
3           subsection (l)(6) against the applicant that  
4           submitted the application for the first ap-  
5           proved interchangeable biosimilar biological  
6           product; or

7           “(ii) the dismissal with or without  
8           prejudice of an action instituted under sub-  
9           section (l)(6) against the applicant that  
10          submitted the application for the first ap-  
11          proved interchangeable biosimilar biological  
12          product; or

13          “(C)(i) 42 months after approval of the first  
14          interchangeable biosimilar biological product if  
15          the applicant that submitted such application  
16          has been sued under subsection (l)(6) and such  
17          litigation is still ongoing within such 36-month  
18          period; or

19          “(ii) 18 months after approval of the first  
20          interchangeable biosimilar biological product if  
21          the applicant that submitted such application  
22          has not been sued under subsection (l)(6).

23          For purposes of this paragraph, the term ‘final court  
24          decision’ means a final decision of a court from which  
25          no appeal (other than a petition to the United States

1 *Supreme Court for a writ of certiorari) has been or*  
2 *can be taken.*

3 “(7) *EXCLUSIVITY FOR REFERENCE PRODUCT.*—

4 “(A) *EFFECTIVE DATE OF BIOSIMILAR AP-*  
5 *PLICATION APPROVAL.*—*Approval of an applica-*  
6 *tion under this subsection may not be made ef-*  
7 *fective by the Secretary until the date that is 12*  
8 *years after the date on which the reference prod-*  
9 *uct was first licensed under subsection (a).*

10 “(B) *FILING PERIOD.*—*An application*  
11 *under this subsection may not be submitted to*  
12 *the Secretary until the date that is 4 years after*  
13 *the date on which the reference product was first*  
14 *licensed under subsection (a).*

15 “(C) *FIRST LICENSURE.*—*The date on*  
16 *which the reference product was first licensed*  
17 *under subsection (a) does not include the date of*  
18 *approval of a supplement or of a subsequent ap-*  
19 *plication for a new indication, route of adminis-*  
20 *tration, dosage form, or strength for the pre-*  
21 *viously licensed reference product.*

22 “(8) *GUIDANCE DOCUMENTS.*—

23 “(A) *IN GENERAL.*—*The Secretary may,*  
24 *after opportunity for public comment, issue*  
25 *guidance in accordance, except as provided in*

1           subparagraph (B)(i), with section 701(h) of the  
2           Federal Food, Drug, and Cosmetic Act with re-  
3           spect to the licensure of a biological product  
4           under this subsection. Any such guidance may be  
5           general or specific.

6           “(B) PUBLIC COMMENT.—

7                   “(i) IN GENERAL.—The Secretary shall  
8                   provide the public an opportunity to com-  
9                   ment on any proposed guidance issued  
10                  under subparagraph (A) before issuing final  
11                  guidance.

12                  “(ii) INPUT REGARDING MOST VALU-  
13                  ABLE GUIDANCE.—The Secretary shall es-  
14                  tablish a process through which the public  
15                  may provide the Secretary with input re-  
16                  garding priorities for issuing guidance.

17           “(C) NO REQUIREMENT FOR APPLICATION  
18           CONSIDERATION.—The issuance (or non-  
19           issuance) of guidance under subparagraph (A)  
20           shall not preclude the review of, or action on, an  
21           application submitted under this subsection.

22           “(D) REQUIREMENT FOR PRODUCT CLASS-  
23           SPECIFIC GUIDANCE.—If the Secretary issues  
24           product class-specific guidance under subpara-

1           *graph (A), such guidance shall include a descrip-*  
2           *tion of—*

3                   “(i) *the criteria that the Secretary will*  
4                   *use to determine whether a biological prod-*  
5                   *uct is highly similar to a reference product*  
6                   *in such product class; and*

7                   “(ii) *the criteria, if available, that the*  
8                   *Secretary will use to determine whether a*  
9                   *biological product meets the standards de-*  
10                  *scribed in paragraph (4).*

11                  “(E) *CERTAIN PRODUCT CLASSES.—*

12                   “(i) *GUIDANCE.—The Secretary may*  
13                   *indicate in a guidance document that the*  
14                   *science and experience, as of the date of*  
15                   *such guidance, with respect to a product or*  
16                   *product class (not including any recom-*  
17                   *binant protein) does not allow approval of*  
18                   *an application for a license as provided*  
19                   *under this subsection for such product or*  
20                   *product class.*

21                   “(ii) *MODIFICATION OR REVERSAL.—*  
22                   *The Secretary may issue a subsequent guid-*  
23                   *ance document under subparagraph (A) to*  
24                   *modify or reverse a guidance document*  
25                   *under clause (i).*

1                   “(iii) *NO EFFECT ON ABILITY TO DENY*  
2                   *LICENSE.—Clause (i) shall not be construed*  
3                   *to require the Secretary to approve a prod-*  
4                   *uct with respect to which the Secretary has*  
5                   *not indicated in a guidance document that*  
6                   *the science and experience, as described in*  
7                   *clause (i), does not allow approval of such*  
8                   *an application.*

9                   “(l) *PATENTS.—*

10                   “(1) *CONFIDENTIAL ACCESS TO SUBSECTION (k)*  
11                   *APPLICATION.—*

12                   “(A) *APPLICATION OF PARAGRAPH.—Unless*  
13                   *otherwise agreed to by a person that submits an*  
14                   *application under subsection (k) (referred to in*  
15                   *this subsection as the ‘subsection (k) applicant’)*  
16                   *and the sponsor of the application for the ref-*  
17                   *erence product (referred to in this paragraph as*  
18                   *the ‘reference product sponsor’), the provisions of*  
19                   *this paragraph shall apply to the exchange of in-*  
20                   *formation described in this subsection.*

21                   “(B) *IN GENERAL.—*

22                   “(i) *PROVISION OF CONFIDENTIAL IN-*  
23                   *FORMATION.—When a subsection (k) appli-*  
24                   *cant submits an application under sub-*  
25                   *section (k), such applicant shall provide to*

1           the persons described in clause (ii), subject  
2           to the terms of this paragraph, confidential  
3           access to the information required to be pro-  
4           duced pursuant to paragraph (2) and any  
5           other information that the subsection (k)  
6           applicant determines, in its sole discretion,  
7           to be appropriate (referred to in this sub-  
8           section as the ‘confidential information’).

9           “(ii) *RECIPIENTS OF INFORMATION.*—

10          *The persons described in this clause are the*  
11          *following:*

12           “(I) *OUTSIDE COUNSEL.*—*One or*  
13           *more attorneys designated by the ref-*  
14           *erence product sponsor who are em-*  
15           *ployees of an entity other than the ref-*  
16           *erence product sponsor (referred to in*  
17           *this paragraph as the ‘outside coun-*  
18           *sel’), provided that such attorneys do*  
19           *not engage, formally or informally, in*  
20           *patent prosecution relevant or related*  
21           *to the reference product.*

22           “(II) *IN-HOUSE COUNSEL.*—*One*  
23           *attorney that represents the reference*  
24           *product sponsor who is an employee of*  
25           *the reference product sponsor, provided*

1           that such attorney does not engage, for-  
2           mally or informally, in patent prosecu-  
3           tion relevant or related to the reference  
4           product.

5           “(iii) *PATENT OWNER ACCESS.*—A rep-  
6           resentative of the owner of a patent exclu-  
7           sively licensed to a reference product spon-  
8           sor with respect to the reference product and  
9           who has retained a right to assert the pat-  
10          ent or participate in litigation concerning  
11          the patent may be provided the confidential  
12          information, provided that the representa-  
13          tive informs the reference product sponsor  
14          and the subsection (k) applicant of his or  
15          her agreement to be subject to the confiden-  
16          tiality provisions set forth in this para-  
17          graph, including those under clause (ii).

18          “(C) *LIMITATION ON DISCLOSURE.*—No per-  
19          son that receives confidential information pursu-  
20          ant to subparagraph (B) shall disclose any con-  
21          fidential information to any other person or en-  
22          tity, including the reference product sponsor em-  
23          ployees, outside scientific consultants, or other  
24          outside counsel retained by the reference product  
25          sponsor, without the prior written consent of the



1 subsection (k) applicant, which shall not be un-  
2 reasonably withheld.

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

14 “(E) OWNERSHIP OF CONFIDENTIAL INFOR-  
15 MATION.—The confidential information disclosed  
16 under this paragraph is, and shall remain, the  
17 property of the subsection (k) applicant. By pro-  
18 viding the confidential information pursuant to  
19 this paragraph, the subsection (k) applicant does  
20 not provide the reference product sponsor or the  
21 outside counsel any interest in or license to use  
22 the confidential information, for purposes other  
23 than those specified in subparagraph (D).

24 “(F) EFFECT OF INFRINGEMENT ACTION.—  
25 In the event that the reference product sponsor

1       *files a patent infringement suit, the use of con-*  
2       *fidential information shall continue to be gov-*  
3       *erned by the terms of this paragraph until such*  
4       *time as a court enters a protective order regard-*  
5       *ing the information. Upon entry of such order,*  
6       *the subsection (k) applicant may redesignate*  
7       *confidential information in accordance with the*  
8       *terms of that order. No confidential information*  
9       *shall be included in any publicly-available com-*  
10      *plaint or other pleading. In the event that the*  
11      *reference product sponsor does not file an in-*  
12      *fringement action by the date specified in para-*  
13      *graph (6), the reference product sponsor shall re-*  
14      *turn or destroy all confidential information re-*  
15      *ceived under this paragraph, provided that if the*  
16      *reference product sponsor opts to destroy such in-*  
17      *formation, it will confirm destruction in writing*  
18      *to the subsection (k) applicant.*

19               “(G) *RULE OF CONSTRUCTION.*—*Nothing in*  
20      *this paragraph shall be construed—*

21                       “(i) *as an admission by the subsection*  
22                       *(k) applicant regarding the validity, en-*  
23                       *forceability, or infringement of any patent;*  
24                       *or*

1                   “(ii) an agreement or admission by the  
2                   subsection (k) applicant with respect to the  
3                   competency, relevance, or materiality of any  
4                   confidential information.

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

14                  “(2) SUBSECTION (k) APPLICATION INFORMA-  
15                  TION.—Not later than 20 days after the Secretary no-  
16                  tifies the subsection (k) applicant that the application  
17                  has been accepted for review, the subsection (k) appli-  
18                  cant—

19                         “(A) shall provide to the reference product  
20                         sponsor a copy of the application submitted to  
21                         the Secretary under subsection (k), and such  
22                         other information that describes the process or  
23                         processes used to manufacture the biological  
24                         product that is the subject of such application;  
25                         and

1           “(B) may provide to the reference product  
2 sponsor additional information requested by or  
3 on behalf of the reference product sponsor.

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

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

10           “(i) a list of patents for which the ref-  
11 erence product sponsor believes a claim of  
12 patent infringement could reasonably be as-  
13 serted by the reference product sponsor, or  
14 by a patent owner that has granted an ex-  
15 clusive license to the reference product spon-  
16 sor with respect to the reference product, if  
17 a person not licensed by the reference prod-  
18 uct sponsor engaged in the making, using,  
19 offering to sell, selling, or importing into  
20 the United States of the biological product  
21 that is the subject of the subsection (k) ap-  
22 plication; and

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

1            *sor would be prepared to license to the sub-*  
2            *section (k) applicant.*

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

7            *“(i) may provide to the reference prod-*  
8            *uct sponsor a list of patents to which the*  
9            *subsection (k) applicant believes a claim of*  
10           *patent infringement could reasonably be as-*  
11           *serted by the reference product sponsor if a*  
12           *person not licensed by the reference product*  
13           *sponsor engaged in the making, using, offer-*  
14           *ing to sell, selling, or importing into the*  
15           *United States of the biological product that*  
16           *is the subject of the subsection (k) applica-*  
17           *tion;*

18           *“(ii) shall provide to the reference*  
19           *product sponsor, with respect to each patent*  
20           *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 commer-  
4           cial marketing of the biological product  
5           that is the subject of the subsection (k)  
6           application; or

7                   “(II) a statement that the sub-  
8                   section (k) applicant does not intend to  
9                   begin commercial marketing of the bio-  
10                  logical 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 re-  
18                  ceipt of the list and statement under subpara-  
19                  graph (B), the reference product sponsor shall  
20                  provide to the subsection (k) applicant a detailed  
21                  statement that describes, with respect to each  
22                  patent described in subparagraph (B)(ii)(I), on  
23                  a claim by claim basis, the factual and legal  
24                  basis of the opinion of the reference product  
25                  sponsor that such patent will be infringed by the

1           *commercial marketing of the biological product*  
2           *that is the subject of the subsection (k) applica-*  
3           *tion and a response to the statement concerning*  
4           *validity and enforceability provided under sub-*  
5           *paragraph (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 sponsor*  
10                   *and the subsection (k) applicant shall engage in*  
11                   *good faith negotiations to agree on which, if any,*  
12                   *patents listed under paragraph (3) by the sub-*  
13                   *section (k) applicant or the reference product*  
14                   *sponsor shall be the subject of an action for pat-*  
15                   *ent infringement under paragraph (6).*

16                   “(B) *FAILURE TO REACH AGREEMENT.*—*If,*  
17                   *within 15 days of beginning negotiations under*  
18                   *subparagraph (A), the subsection (k) applicant*  
19                   *and the reference product sponsor fail to agree on*  
20                   *a final and complete list of which, if any, pat-*  
21                   *ents listed under paragraph (3) by the subsection*  
22                   *(k) applicant or the reference product sponsor*  
23                   *shall be the subject of an action for patent in-*  
24                   *fringement under paragraph (6), the provisions*  
25                   *of paragraph (5) shall apply to the parties.*

1           “(5) *PATENT RESOLUTION IF NO AGREEMENT.*—

2           “(A) *NUMBER OF PATENTS.*—*The subsection*  
3           *(k) applicant shall notify the reference product*  
4           *sponsor of the number of patents that such appli-*  
5           *cant will provide to the reference product sponsor*  
6           *under subparagraph (B)(i)(I).*

7           “(B) *EXCHANGE OF PATENT LISTS.*—

8           “(i) *IN GENERAL.*—*On a date agreed*  
9           *to by the subsection (k) applicant and the*  
10           *reference product sponsor, but in no case*  
11           *later than 5 days after the subsection (k)*  
12           *application notifies the reference product*  
13           *sponsor under subparagraph (A), the sub-*  
14           *section (k) applicant and the reference prod-*  
15           *uct sponsor shall simultaneously exchange—*

16           “(I) *the list of patents that the*  
17           *subsection (k) applicant believes should*  
18           *be the subject of an action for patent*  
19           *infringement under paragraph (6);*  
20           *and*

21           “(II) *the list of patents, in accord-*  
22           *ance with clause (ii), that the reference*  
23           *product sponsor believes should be the*  
24           *subject of an action for patent in-*  
25           *fringement under paragraph (6).*



1                   “(i) NUMBER OF PATENTS LISTED BY  
2                   REFERENCE PRODUCT SPONSOR.—

3                   “(I) IN GENERAL.—Subject to  
4                   subclause (II), the number of patents  
5                   listed by the reference product sponsor  
6                   under clause (i)(II) may not exceed the  
7                   number of patents listed by the sub-  
8                   section (k) applicant under clause  
9                   (i)(I).

10                  “(II) EXCEPTION.—If a subsection  
11                  (k) applicant does not list any patent  
12                  under clause (i)(I), the reference prod-  
13                  uct sponsor may list 1 patent under  
14                  clause (i)(II).

15                  “(6) IMMEDIATE PATENT INFRINGEMENT AC-  
16                  TION.—

17                  “(A) ACTION IF AGREEMENT ON PATENT  
18                  LIST.—If the subsection (k) applicant and the  
19                  reference product sponsor agree on patents as de-  
20                  scribed in paragraph (4), not later than 30 days  
21                  after such agreement, the reference product spon-  
22                  sor shall bring an action for patent infringement  
23                  with respect to each such patent.

24                  “(B) ACTION IF NO AGREEMENT ON PATENT  
25                  LIST.—If the provisions of paragraph (5) apply

1           to the parties as described in paragraph (4)(B),  
2           not later than 30 days after the exchange of lists  
3           under paragraph (5)(B), the reference product  
4           sponsor shall bring an action for patent in-  
5           fringement with respect to each patent that is in-  
6           cluded on such lists.

7           “(C) NOTIFICATION AND PUBLICATION OF  
8           COMPLAINT.—

9           “(i) NOTIFICATION TO SECRETARY.—

10           Not later than 30 days after a complaint is  
11           served to a subsection (k) applicant in an  
12           action for patent infringement described  
13           under this paragraph, the subsection (k) ap-  
14           plicant shall provide the Secretary with no-  
15           tice and a copy of such complaint.

16           “(ii) PUBLICATION BY SECRETARY.—

17           The Secretary shall publish in the Federal  
18           Register notice of a complaint received  
19           under clause (i).

20           “(7) NEWLY ISSUED OR LICENSED PATENTS.—In  
21           the case of a patent that—

22           “(A) is issued to, or exclusively licensed by,  
23           the reference product sponsor after the date that  
24           the reference product sponsor provided the list to

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

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

22           “(8) NOTICE OF COMMERCIAL MARKETING AND  
23          PRELIMINARY INJUNCTION.—

24           “(A) NOTICE OF COMMERCIAL MAR-  
25          KETING.—The subsection (k) applicant shall pro-

1           *vide notice to the reference product sponsor not*  
2           *later than 180 days before the date of the first*  
3           *commercial marketing of the biological product*  
4           *licensed under subsection (k).*

5           “(B) *PRELIMINARY INJUNCTION.*—*After re-*  
6           *ceiving the notice under subparagraph (A) and*  
7           *before such date of the first commercial mar-*  
8           *keting of such biological product, the reference*  
9           *product sponsor may seek a preliminary injunc-*  
10          *tion prohibiting the subsection (k) applicant*  
11          *from engaging in the commercial manufacture or*  
12          *sale of such biological product until the court de-*  
13          *cides the issue of patent validity, enforcement,*  
14          *and infringement with respect to any patent that*  
15          *is—*

16                 “(i) *included in the list provided by*  
17                 *the reference product sponsor under para-*  
18                 *graph (3)(A) or in the list provided by the*  
19                 *subsection (k) applicant under paragraph*  
20                 *(3)(B); and*

21                 “(ii) *not included, as applicable, on—*

22                         “(I) *the list of patents described*  
23                         *in paragraph (4); or*

24                         “(II) *the lists of patents described*  
25                         *in paragraph (5)(B).*

1           “(C) *REASONABLE COOPERATION.*—If the  
2           reference product sponsor has sought a prelimi-  
3           nary injunction under subparagraph (B), the  
4           reference product sponsor and the subsection (k)  
5           applicant shall reasonably cooperate to expedite  
6           such further discovery as is needed in connection  
7           with the preliminary injunction motion.

8           “(9) *LIMITATION ON DECLARATORY JUDGMENT*  
9           *ACTION.*—

10           “(A) *SUBSECTION (k) APPLICATION PRO-*  
11           *VIDED.*—If a subsection (k) applicant provides  
12           the application and information required under  
13           paragraph (2)(A), neither the reference product  
14           sponsor nor the subsection (k) applicant may,  
15           prior to the date notice is received under para-  
16           graph (8)(A), bring any action under section  
17           2201 of title 28, United States Code, for a dec-  
18           laration of infringement, validity, or enforce-  
19           ability of any patent that is described in clauses  
20           (i) and (ii) of paragraph (8)(B).

21           “(B) *SUBSEQUENT FAILURE TO ACT BY*  
22           *SUBSECTION (k) APPLICANT.*—If a subsection (k)  
23           applicant fails to complete an action required of  
24           the subsection (k) applicant under paragraph  
25           (3)(B)(ii), paragraph (5), paragraph (6)(C)(i),

1 paragraph (7), or paragraph (8)(A), the ref-  
2 erence product sponsor, but not the subsection (k)  
3 applicant, may bring an action under section  
4 2201 of title 28, United States Code, for a dec-  
5 laration of infringement, validity, or enforce-  
6 ability of any patent included in the list de-  
7 scribed in paragraph (3)(A), including as pro-  
8 vided under paragraph (7).

9 “(C) SUBSECTION (k) APPLICATION NOT  
10 PROVIDED.—If a subsection (k) applicant fails to  
11 provide the application and information re-  
12 quired under paragraph (2)(A), the reference  
13 product sponsor, but not the subsection (k) appli-  
14 cant, may bring an action under section 2201 of  
15 title 28, United States Code, for a declaration of  
16 infringement, validity, or enforceability of any  
17 patent that claims the biological product or a use  
18 of the biological product.”

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

21 (1) by striking “In this section, the term ‘biologi-  
22 cal product’ means” and inserting the following: “In  
23 this section:

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

1           (2) *in paragraph (1), as so designated, by insert-*  
2           *ing “protein (except any chemically synthesized*  
3           *polypeptide),” after “allergenic product,”; and*

4           (3) *by adding at the end the following:*

5           “(2) *The term ‘biosimilar’ or ‘biosimilarity’, in*  
6           *reference to a biological product that is the subject of*  
7           *an application under subsection (k), means—*

8                   “(A) *that the biological product is highly*  
9                   *similar to the reference product notwithstanding*  
10                   *minor differences in clinically inactive compo-*  
11                   *nents; and*

12                   “(B) *there are no clinically meaningful dif-*  
13                   *ferences between the biological product and the*  
14                   *reference product in terms of the safety, purity,*  
15                   *and potency of the product.*

16           “(3) *The term ‘interchangeable’ or ‘interchange-*  
17           *ability’, in reference to a biological product that is*  
18           *shown to meet the standards described in subsection*  
19           *(k)(4), means that the biological product may be sub-*  
20           *stituted for the reference product without the interven-*  
21           *tion of the health care provider who prescribed the*  
22           *reference product.*

23           “(4) *The term ‘reference product’ means the sin-*  
24           *gle biological product licensed under subsection (a)*

1       *against which a biological product is evaluated in an*  
2       *application submitted under subsection (k).”.*

3       (c) *CONFORMING AMENDMENTS RELATING TO PAT-*  
4       *ENTS.—*

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

7                       (A) *in paragraph (2)—*

8                               (i) *in subparagraph (A), by striking*  
9                               “or” *at the end;*

10                              (ii) *in subparagraph (B), by adding*  
11                              “or” *at the end; and*

12                              (iii) *by inserting after subparagraph*  
13                              (B) *the following:*

14                              “(C)(i) *with respect to a patent that is identified*  
15       *in the list of patents described in section 351(l)(3) of*  
16       *the Public Health Service Act (including as provided*  
17       *under section 351(l)(7) of such Act), an application*  
18       *seeking approval of a biological product, or*

19                              “(ii) *if the applicant for the application fails to*  
20       *provide the application and information required*  
21       *under section 351(l)(2)(A) of such Act, an application*  
22       *seeking approval of a biological product for a patent*  
23       *that could be identified pursuant to section*  
24       *351(l)(3)(A)(i) of such Act,”; and*



1                   (iv) in the matter following subpara-  
2                   graph (C) (as added by clause (iii)), by  
3                   striking “or veterinary biological product”  
4                   and inserting “, veterinary biological prod-  
5                   uct, or biological product”;

6                   (B) in paragraph (4)—

7                   (i) in subparagraph (B), by—

8                   (I) striking “or veterinary biologi-  
9                   cal product” and inserting “, veteri-  
10                  nary biological product, or biological  
11                  product”; and

12                  (II) striking “and” at the end;

13                  (ii) in subparagraph (C), by—

14                  (I) striking “or veterinary biologi-  
15                  cal product” and inserting “, veteri-  
16                  nary biological product, or biological  
17                  product”; and

18                  (II) striking the period and in-  
19                  serting “, and”;

20                  (iii) by inserting after subparagraph

21                  (C) the following:

22                  “(D) the court shall order a permanent injunc-  
23                  tion prohibiting any infringement of the patent by  
24                  the biological product involved in the infringement  
25                  until a date which is not earlier than the date of the

1 *expiration of the patent that has been infringed under*  
2 *paragraph (2)(C), provided the patent is the subject*  
3 *of a final court decision, as defined in section*  
4 *351(k)(6) of the Public Health Service Act, in an ac-*  
5 *tion for infringement of the patent under section*  
6 *351(l)(6) of such Act, and the biological product has*  
7 *not yet been approved because of section 351(k)(7) of*  
8 *such Act.”; and*

9 *(iv) in the matter following subpara-*  
10 *graph (D) (as added by clause (iii)), by*  
11 *striking “and (C)” and inserting “(C), and*  
12 *(D)”;* and

13 *(C) by adding at the end the following:*

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

16 *“(i) that is identified, as applicable, in the list*  
17 *of patents described in section 351(l)(4) of the Public*  
18 *Health Service Act or the lists of patents described in*  
19 *section 351(l)(5)(B) of such Act with respect to a bio-*  
20 *logical product; and*

21 *“(ii) for which an action for infringement of the*  
22 *patent with respect to the biological product—*

23 *“(I) was brought after the expiration of the*  
24 *30-day period described in subparagraph (A) or*

1           (B), as applicable, of section 351(l)(6) of such  
2           Act; or

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

7           “(B) In an action for infringement of a patent de-  
8           scribed in subparagraph (A), the sole and exclusive remedy  
9           that may be granted by a court, upon a finding that the  
10          making, using, offering to sell, selling, or importation into  
11          the United States of the biological product that is the subject  
12          of the action infringed the patent, shall be a reasonable roy-  
13          alty.

14          “(C) The owner of a patent that should have been in-  
15          cluded in the list described in section 351(l)(3)(A) of the  
16          Public Health Service Act, including as provided under sec-  
17          tion 351(l)(7) of such Act for a biological product, but was  
18          not timely included in such list, may not bring an action  
19          under this section for infringement of the patent with re-  
20          spect to the biological product.”.

21                   (2) CONFORMING AMENDMENT UNDER TITLE  
22          28.—Section 2201(b) of title 28, United States Code,  
23          is amended by inserting before the period the fol-  
24          lowing: “, or section 351 of the Public Health Service  
25          Act”.

1           (d) *CONFORMING AMENDMENTS UNDER THE FEDERAL*  
2 *FOOD, DRUG, AND COSMETIC ACT.*—

3           (1) *CONTENT AND REVIEW OF APPLICATIONS.*—

4           Section 505(b)(5)(B) of the Federal Food, Drug, and  
5           Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by  
6           inserting before the period at the end of the first sen-  
7           tence the following: “or, with respect to an applicant  
8           for approval of a biological product under section  
9           351(k) of the Public Health Service Act, any nec-  
10          essary clinical study or studies”.

11          (2) *NEW ACTIVE INGREDIENT.*—Section 505B of  
12          the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13          355c) is amended by adding at the end the following:

14          “(i) *NEW ACTIVE INGREDIENT.*—

15               “(1) *NON-INTERCHANGEABLE BIOSIMILAR BIO-*  
16               *LOGICAL PRODUCT.*—A biological product that is bio-  
17               similar to a reference product under section 351 of the  
18               Public Health Service Act, and that the Secretary has  
19               not determined to meet the standards described in  
20               subsection (k)(4) of such section for interchangeability  
21               with the reference product, shall be considered to have  
22               a new active ingredient under this section.

23               “(2) *INTERCHANGEABLE BIOSIMILAR BIOLOGICAL*  
24               *PRODUCT.*—A biological product that is interchange-  
25               able with a reference product under section 351 of the

1       *Public Health Service Act shall not be considered to*  
2       *have a new active ingredient under this section.”.*

3       *(e) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-*  
4       *TION 505.—*

5               *(1) REQUIREMENT TO FOLLOW SECTION 351.—*  
6       *Except as provided in paragraph (2), an application*  
7       *for a biological product shall be submitted under sec-*  
8       *tion 351 of the Public Health Service Act (42 U.S.C.*  
9       *262) (as amended by this Act).*

10              *(2) EXCEPTION.—An application for a biological*  
11       *product may be submitted under section 505 of the*  
12       *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
13       *355) if—*

14                      *(A) such biological product is in a product*  
15       *class for which a biological product in such*  
16       *product class is the subject of an application ap-*  
17       *proved under such section 505 not later than the*  
18       *date of enactment of this Act; and*

19                      *(B) such application—*

20                              *(i) has been submitted to the Secretary*  
21       *of Health and Human Services (referred to*  
22       *in this Act as the “Secretary”) before the*  
23       *date of enactment of this Act; or*

1                   (ii) is submitted to the Secretary not  
2                   later than the date that is 10 years after the  
3                   date of enactment of this Act.

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

14                  (4) *DEEMED APPROVED UNDER SECTION 351.*—  
15                  An approved application for a biological product  
16                  under section 505 of the Federal Food, Drug, and  
17                  Cosmetic Act (21 U.S.C. 355) shall be deemed to be  
18                  a license for the biological product under such section  
19                  351 on the date that is 10 years after the date of en-  
20                  actment of this Act.

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

1       (f) *FOLLOW-ON BIOLOGICS USER FEES.*—

2               (1) *DEVELOPMENT OF USER FEES FOR BIO-*  
3 *SIMILAR BIOLOGICAL PRODUCTS.*—

4               (A) *IN GENERAL.*—*Beginning not later than*  
5 *October 1, 2010, the Secretary shall develop rec-*  
6 *ommendations to present to Congress with re-*  
7 *spect to the goals, and plans for meeting the*  
8 *goals, for the process for the review of biosimilar*  
9 *biological product applications submitted under*  
10 *section 351(k) of the Public Health Service Act*  
11 *(as added by this Act) for the first 5 fiscal years*  
12 *after fiscal year 2012. In developing such rec-*  
13 *ommendations, the Secretary shall consult*  
14 *with—*

15                       (i) *the Committee on Health, Edu-*  
16 *cation, Labor, and Pensions of the Senate;*

17                       (ii) *the Committee on Energy and*  
18 *Commerce of the House of Representatives;*

19                       (iii) *scientific and academic experts;*

20                       (iv) *health care professionals;*

21                       (v) *representatives of patient and con-*  
22 *sumer advocacy groups; and*

23                       (vi) *the regulated industry.*

1           (B) *PUBLIC REVIEW OF RECOMMENDA-*  
2           *TIONS.—After negotiations with the regulated in-*  
3           *dustry, the Secretary shall—*

4                   (i) *present the recommendations devel-*  
5                   *oped under subparagraph (A) to the Con-*  
6                   *gressional committees specified in such sub-*  
7                   *paragraph;*

8                   (ii) *publish such recommendations in*  
9                   *the Federal Register;*

10                  (iii) *provide for a period of 30 days for*  
11                  *the public to provide written comments on*  
12                  *such recommendations;*

13                  (iv) *hold a meeting at which the public*  
14                  *may present its views on such recommenda-*  
15                  *tions; and*

16                  (v) *after consideration of such public*  
17                  *views and comments, revise such rec-*  
18                  *ommendations as necessary.*

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



1           *made to the recommendations in response to such*  
2           *views and comments.*

3           (2) *ESTABLISHMENT OF USER FEE PROGRAM.—*

4           *It is the sense of the Senate that, based on the rec-*  
5           *ommendations transmitted to Congress by the Sec-*  
6           *retary pursuant to paragraph (1)(C), Congress should*  
7           *authorize a program, effective on October 1, 2012, for*  
8           *the collection of user fees relating to the submission of*  
9           *biosimilar biological product applications under sec-*  
10          *tion 351(k) of the Public Health Service Act (as*  
11          *added by this Act).*

12          (3) *TRANSITIONAL PROVISIONS FOR USER FEES*  
13          *FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—*

14                (A) *APPLICATION OF THE PRESCRIPTION*  
15                *DRUG USER FEE PROVISIONS.—Section*  
16                *735(1)(C) of the Federal Food, Drug, and Cos-*  
17                *metic Act (21 U.S.C. 379g(1)(C)) is amended by*  
18                *striking “section 351” and inserting “subsection*  
19                *(a) or (k) of section 351”.*

20                (B) *EVALUATION OF COSTS OF REVIEWING*  
21                *BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-*  
22                *TIONS.—During the period beginning on the date*  
23                *of enactment of this Act and ending on October*  
24                *1, 2010, the Secretary shall collect and evaluate*  
25                *data regarding the costs of reviewing applica-*

1           *tions for biological products submitted under sec-*  
2           *tion 351(k) of the Public Health Service Act (as*  
3           *added by this Act) during such period.*

4           (C) *AUDIT.*—

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

15                (I) *the costs of reviewing such ap-*  
16                *plications under such section 351(k) to*  
17                *the amount of the user fee applicable to*  
18                *such applications; and*

19                (II)(aa) *such ratio determined*  
20                *under subclause (I); to*

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

1                    *such applications under such section*  
2                    *351(a).*

3                    *(ii) ALTERATION OF USER FEE.—If the*  
4                    *audit performed under clause (i) indicates*  
5                    *that the ratios compared under subclause*  
6                    *(II) of such clause differ by more than 5*  
7                    *percent, then the Secretary shall alter the*  
8                    *user fee applicable to applications sub-*  
9                    *mitted under such section 351(k) to more*  
10                   *appropriately account for the costs of re-*  
11                   *viewing such applications.*

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

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

24                   *(g) ALLOCATION OF SAVINGS; SPECIAL RESERVE*  
25                   *FUND.—*

1           (1) *DETERMINATION OF SAVINGS.*—*The Sec-*  
2 *retary of the Treasury, in consultation with the Sec-*  
3 *retary, shall for each fiscal year determine the*  
4 *amount of the savings to the Federal Government as*  
5 *a result of the enactment of this Act and shall trans-*  
6 *fer such amount to the Fund established under para-*  
7 *graph (2) pursuant to a relevant appropriations Act.*

8           (2) *SPECIAL RESERVE FUND.*—

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

14           (B) *USE OF FUND.*—*The amounts made*  
15 *available to the Secretary through the Fund*  
16 *under subparagraph (A) shall be expended on ac-*  
17 *tivities authorized under the Public Health Serv-*  
18 *ice Act.*

19           (3) *AUTHORIZATION OF APPROPRIATIONS.*—  
20 *There is authorized to be appropriated for each fiscal*  
21 *year to the Fund established under paragraph (2), the*  
22 *amount of the savings determined for such fiscal year*  
23 *under paragraph (1).*

24           (h) *GOVERNMENT ACCOUNTABILITY OFFICE STUDY.*—

1           (1) *IN GENERAL.*—Not later than 3 years after  
2           the date of enactment of this Act, the Comptroller  
3           General of the United States shall study and report  
4           to Congress regarding—

5                   (A) the extent to which pediatric studies of  
6                   biological products are being required under the  
7                   Federal Food, Drug, and Cosmetic Act (21  
8                   U.S.C. 301 et seq.); and

9                   (B) any pediatric needs not being met  
10                  under existing authority.

11           (2) *CONTENT OF STUDY.*—The study under para-  
12           graph (1) shall review and assess—

13                   (A) the extent to which pediatric studies of  
14                   biological products are required under sub-  
15                   sections (a) and (b) of section 505B of the Fed-  
16                   eral Food, Drug and Cosmetic Act (21 U.S.C.  
17                   355c);

18                   (B) the extent to which pediatric studies of  
19                   biological products are required as part of risk  
20                   evaluation and mitigation strategies under such  
21                   Act;

22                   (C) the number, importance, and  
23                   prioritization of any biological products that are  
24                   not being tested for pediatric use; and

1                   (D) recommendations for ensuring pediatric  
2                   testing of products identified in subparagraph  
3                   (C), including the consideration of any incen-  
4                   tives, such as those provided under the Best  
5                   Pharmaceuticals for Children Act.

6           (i) ORPHAN PRODUCTS.—If a reference product, as de-  
7           fined in section 351 of the Public Health Service Act (42  
8           U.S.C. 262) (as amended by this Act) has been designated  
9           under section 526 of the Federal Food, Drug, and Cosmetic  
10          Act (21 U.S.C. 360bb) for a rare disease or condition, a  
11          biological product seeking approval for such disease or con-  
12          dition under subsection (k) of such section 351 as biosimilar  
13          to, or interchangeable with, such reference product may be  
14          licensed by the Secretary only after the expiration for such  
15          reference product of the later of—

16               (1) the 7-year period described in section 527(a)  
17               of the Federal Food, Drug, and Cosmetic Act (21  
18               U.S.C. 360cc(a)); and

19               (2) the 12-year period described in subsection  
20               (k)(7) of such section 351.



Calendar No. 1127

110<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**S. 1695**

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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.

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NOVEMBER 19, 2008

Reported with an amendment