

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To establish a pathway for the licensure of bio-similar biological products and to promote innovation in the life sciences.

**IN THE SENATE OF THE UNITED STATES—111th Cong., 1st Sess.**

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

To make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce.

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by  
\_\_\_\_\_

Viz:

- 1 On page 596, after line 17, insert the following:
- 2 **SEC. 601. SHORT TITLE.**
- 3 This subtitle may be cited as the “Biologics Price
- 4 Competition and Innovation Act of 2009”.

1 **SEC. 602. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGI-**  
2 **CAL PRODUCTS.**

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

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

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

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

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

15 “(2) CONTENT.—

16 “(A) IN GENERAL.—

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

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

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

1 reference product notwith-  
2 standing minor differences in  
3 clinically inactive components;

4 “(bb) animal studies (includ-  
5 ing the assessment of toxicity);  
6 and

7 “(cc) a clinical study or  
8 studies (including the assessment  
9 of immunogenicity and phar-  
10 macokinetics or  
11 pharmacodynamics) that are suf-  
12 ficient to demonstrate safety, pu-  
13 rity, and potency in 1 or more  
14 appropriate conditions of use for  
15 which the reference product is li-  
16 censed and intended to be used  
17 and for which licensure is sought  
18 for the biological product;

19 “(II) the biological product and  
20 reference product utilize the same  
21 mechanism or mechanisms of action  
22 for the condition or conditions of use  
23 prescribed, recommended, or sug-  
24 gested in the proposed labeling, but  
25 only to the extent the mechanism or

1 mechanisms of action are known for  
2 the reference product;

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

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

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

20 “(ii) DETERMINATION BY SEC-  
21 RETARY.—The Secretary may determine,  
22 in the Secretary’s discretion, that an ele-  
23 ment described in clause (i)(I) is unneces-  
24 sary in an application submitted under this  
25 subsection.

1 “(iii) ADDITIONAL INFORMATION.—

2 An application submitted under this sub-  
3 section—

4 “(I) shall include publicly-avail-  
5 able information regarding the Sec-  
6 retary’s previous determination that  
7 the reference product is safe, pure,  
8 and potent; and

9 “(II) may include any additional  
10 information in support of the applica-  
11 tion, including publicly-available infor-  
12 mation with respect to the reference  
13 product or another biological product.

14 “(B) INTERCHANGEABILITY.—An applica-  
15 tion (or a supplement to an application) sub-  
16 mitted under this subsection may include infor-  
17 mation demonstrating that the biological prod-  
18 uct meets the standards described in paragraph  
19 (4).

20 “(3) EVALUATION BY SECRETARY.—Upon re-  
21 view of an application (or a supplement to an appli-  
22 cation) submitted under this subsection, the Sec-  
23 retary shall license the biological product under this  
24 subsection if—

1           “(A) the Secretary determines that the in-  
2           formation submitted in the application (or the  
3           supplement) is sufficient to show that the bio-  
4           logical product—

5                   “(i) is biosimilar to the reference  
6                   product; or

7                   “(ii) meets the standards described in  
8                   paragraph (4), and therefore is inter-  
9                   changeable with the reference product; and

10           “(B) the applicant (or other appropriate  
11           person) consents to the inspection of the facility  
12           that is the subject of the application, in accord-  
13           ance with subsection (c).

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

23                   “(A) the biological product—

24                   “(i) is biosimilar to the reference  
25                   product; and

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

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

11                 “(5) GENERAL RULES.—

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

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

23                   “(C) RISK EVALUATION AND MITIGATION  
24                   STRATEGIES.—The authority of the Secretary  
25                   with respect to risk evaluation and mitigation

1 strategies under the Federal Food, Drug, and  
2 Cosmetic Act shall apply to biological products  
3 licensed under this subsection in the same man-  
4 ner as such authority applies to biological prod-  
5 ucts licensed under subsection (a).

6 “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-  
7 ABLE BIOLOGICAL PRODUCT.—

8 “(A) IN GENERAL.—Upon review of an ap-  
9 plication submitted under this subsection rely-  
10 ing on the same reference product for which a  
11 prior biological product has received a deter-  
12 mination of interchangeability for any condition  
13 of use, the Secretary shall not make a deter-  
14 mination under paragraphs (3)(A)(ii) and (4)  
15 that the second or subsequent biological product  
16 is interchangeable for any condition of use until  
17 the earlier of—

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

23 “(ii) 18 months after—

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



1 under subsection (l)(6) against the  
2 applicant that submitted the applica-  
3 tion for the first approved inter-  
4 changeable biosimilar biological prod-  
5 uct; or

6 “(II) the dismissal with or with-  
7 out prejudice of an action instituted  
8 under subsection (l)(6) against the  
9 applicant that submitted the applica-  
10 tion for the first approved inter-  
11 changeable biosimilar biological prod-  
12 uct; or

13 “(iii)(I) 42 months after approval of  
14 the first interchangeable biosimilar biologi-  
15 cal product if the applicant that submitted  
16 such application has been sued under sub-  
17 section (l)(6) and such litigation is still on-  
18 going within such 42-month period; or

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

24 For purposes of this subparagraph, the term ‘final  
25 court decision’ means a final decision of a court

1 from which no appeal (other than a petition to the  
2 United States Supreme Court for a writ of certio-  
3 rari) has been or can be taken.

4 “(B) NO EFFECT ON BIOSIMILARITY DE-  
5 TERMINATION.—Subparagraph (A) shall not  
6 prevent the Secretary from—

7 “(i) making a determination under  
8 paragraph (3)(A)(i) that the second or  
9 subsequent biological product is biosimilar  
10 to the reference product; and

11 “(ii) issuing a license for the second  
12 or subsequent biological product.

13 “(7) EXCLUSIVITY FOR REFERENCE PROD-  
14 UCT.—

15 “(A) EXCLUSIVITY.—

16 “(i) BASE PERIOD.—If an application  
17 under this subsection refers to a biological  
18 product described in clause (i) of subpara-  
19 graph (B), the Secretary may not approve  
20 such application before the expiration of—

21 “(I) the 9-year period beginning  
22 on such product’s approval date;

23 “(II) such period, as extended  
24 under subparagraph (D), if so ex-  
25 tended; or

1                   “(III) such period, as extended  
2                   under subparagraph (E), if so ex-  
3                   tended.

4                   “(ii) NEW INDICATIONS.—If an appli-  
5                   cation under this subsection refers to a bi-  
6                   ological product described in subparagraph  
7                   (C), the Secretary may not approve such  
8                   application for the conditions of approval  
9                   of such product before the expiration of—

10                   “(I) the 2-year period beginning  
11                   on such product’s approval date;

12                   “(II) such period, as extended  
13                   under subparagraph (D), if so ex-  
14                   tended;

15                   “(III) such period, as extended  
16                   under subparagraph (E), if so ex-  
17                   tended.

18                   “(B) NO MAJOR SUBSTANCE PREVIOUSLY  
19                   APPROVED.—

20                   “(i) IN GENERAL.—A biological prod-  
21                   uct is described in this clause if—

22                   “(I) an application is submitted  
23                   for such product under subsection (a);

24                   “(II) no major substance of the  
25                   product, nor any highly similar major

1 substance, has been approved in any  
2 other application under subsection (a);

3 “(III) the application submitted  
4 for such product is approved after the  
5 date of the enactment of this sub-  
6 section; and

7 “(IV) the application submitted  
8 for such product could not and did  
9 not rely on any clinical safety, purity,  
10 or potency study in any other applica-  
11 tion approved under this section or  
12 any clinical safety or effectiveness  
13 study in any application approved  
14 under section 505 of the Federal  
15 Food, Drug, and Cosmetic Act.

16 “(ii) EXCLUSIONS.—Biological prod-  
17 ucts not described in clause (i) include the  
18 following:

19 “(I) Protein biological products  
20 that differ in structure solely due to  
21 minor post-translational changes, or  
22 minor changes in amino acid se-  
23 quence.

24 “(II) Polysaccharide biological  
25 products with similar saccharide re-

1 peating units, even if the number of  
2 units differ and even if there are dif-  
3 ferences in post-polymerization modi-  
4 fications.

5 “(III) Glycosylated protein prod-  
6 ucts that differ in structure solely due  
7 to minor changes in the structure or  
8 number of saccharide moieties.

9 “(IV) Polynucleotide biological  
10 products with identical sequence of  
11 purine and pyrimidine bases (or their  
12 derivatives) bound to an identical  
13 sugar backbone (ribose, deoxyribose,  
14 or modifications of these sugars).

15 The Secretary may by regulation identify addi-  
16 tional biological products not described in  
17 clause (i).

18 “(C) NEW INDICATIONS FOR APPROVED  
19 PRODUCTS.—A biological product is described  
20 in this subparagraph if—

21 “(i) an application is submitted for  
22 such product under subsection (a);

23 “(ii) such product includes a major  
24 substance that has been approved in an-

1 other application under subsection (a), or  
2 any highly similar major substance;

3 “(iii) the application submitted for  
4 such product is approved after the date of  
5 the enactment of this subsection;

6 “(iv) the application submitted for  
7 such product contains reports of new clin-  
8 ical investigations (other than pharmaco-  
9 kinetic or pharmacodynamic studies) es-  
10 sential to the approval of the application  
11 and conducted or sponsored by the appli-  
12 cant; and

13 “(v) the product represents a signifi-  
14 cant therapeutic advance, which may in-  
15 clude demonstration of safety, purity, and  
16 potency for a significant new indication or  
17 subpopulation, other than a pediatric sub-  
18 population.

19 “(D) FIRST PERIOD OF BONUS EXCLU-  
20 SIVITY FOR SIGNIFICANT INNOVATION.—If a  
21 supplement to an application approved under  
22 subsection (a) is approved no later than 1 year  
23 before the expiration of a period to which the  
24 applicant is entitled under subparagraph (A),

1 the period described in subparagraph (A) shall  
2 be extended by 3 years if—

3 “(i) the supplement contains reports  
4 of new clinical investigations (other than  
5 pharmacokinetic or pharmacodynamic  
6 studies) essential to the approval of the  
7 supplement and conducted or sponsored by  
8 the person submitting the supplement; and

9 “(ii) the product that is the subject of  
10 the supplement provides a significant  
11 therapeutic advance, which may include  
12 demonstration of safety, purity, and po-  
13 tency for a significant new indication or  
14 subpopulation, other than a pediatric sub-  
15 population.

16 “(E) SECOND PERIOD OF BONUS EXCLU-  
17 SIVITY FOR SIGNIFICANT INNOVATION.—If a  
18 supplement to an application approved under  
19 subsection (a) is approved no later than 1 year  
20 before the expiration of a period to which the  
21 applicant is entitled under subparagraph (A)  
22 (as extended under subparagraph (D), if so ex-  
23 tended), the period described in subparagraph  
24 (A) (as extended under subparagraph (D), if so  
25 extended) shall be extended by 1 year if—

1           “(i) the supplement contains reports  
2 of new clinical investigations (other than  
3 pharmacokinetic or pharmacodynamic  
4 studies) essential to the approval of the  
5 supplement and conducted or sponsored by  
6 the person submitting the supplement; and

7           “(ii) the product that is the subject of  
8 the supplement provides a significant  
9 therapeutic advance, which may include  
10 demonstration of safety, purity, and po-  
11 tency for a significant new indication or  
12 subpopulation, other than a pediatric sub-  
13 population.

14           “(F) LIMITATION ON RENEWAL OF BONUS  
15 PERIODS.—

16           “(i) ONLY ONE FIRST BONUS PE-  
17 RIOD.—Only 1 extension under subpara-  
18 graph (D) may be granted for any biologi-  
19 cal product.

20           “(ii) ONLY ONE SECOND BONUS PE-  
21 RIOD.—Only 1 extension under subpara-  
22 graph (E) may be granted for any biologi-  
23 cal product.

24           “(8) GUIDANCE DOCUMENTS.—



1           “(A) IN GENERAL.—The Secretary may,  
2           after opportunity for public comment, issue  
3           guidance in accordance, except as provided in  
4           subparagraph (B)(i), with section 701(h) of the  
5           Federal Food, Drug, and Cosmetic Act with re-  
6           spect to the licensure of a biological product  
7           under this subsection. Any such guidance may  
8           be general or specific.

9           “(B) PUBLIC COMMENT.—

10           “(i) IN GENERAL.—The Secretary  
11           shall provide the public an opportunity to  
12           comment on any proposed guidance issued  
13           under subparagraph (A) before issuing  
14           final guidance.

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

20           “(C) NO REQUIREMENT FOR APPLICATION  
21           REVIEW OR ACTION.—The issuance (or non-  
22           issuance) of guidance under subparagraph (A)  
23           shall not preclude the review of, or action on,  
24           an application submitted under this subsection.

1           “(D) REQUIREMENT FOR PRODUCT CLASS-  
2 SPECIFIC GUIDANCE.—If the Secretary issues  
3 product class-specific guidance under subpara-  
4 graph (A), such guidance shall include a de-  
5 scription of—

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

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

14           “(E) CERTAIN PRODUCT CLASSES.—

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

24           “(ii) MODIFICATION OR REVERSAL.—  
25 The Secretary may issue a subsequent

1 guidance document under subparagraph  
2 (A) to modify or reverse a guidance docu-  
3 ment under clause (i).

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

12 “(9) NO CHANGE TO EXISTING STATE LAW.—  
13 Nothing in this subsection or subsection (i)(3) shall  
14 be construed to limit the extent to which substi-  
15 tution of 1 biological product for another biological  
16 product is otherwise permitted or restricted under  
17 applicable State or local law.

18 “(l) PATENTS.—

19 “(1) CONFIDENTIAL ACCESS TO SUBSECTION  
20 (k) APPLICATION.—

21 “(A) APPLICATION OF PARAGRAPH.—Un-  
22 less otherwise agreed to by a person that sub-  
23 mits an application under subsection (k) (re-  
24 ferred to in this subsection as the ‘subsection  
25 (k) applicant’) and the sponsor of the applica-



1            ployees of an entity other than the  
2            reference product sponsor (referred to  
3            in this paragraph as the ‘outside  
4            counsel’), provided that such attor-  
5            neys do not engage, formally or infor-  
6            mally, in patent prosecution relevant  
7            or related to the reference product.

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

16           “(iii) PATENT OWNER ACCESS.—A  
17           representative of the owner of a patent ex-  
18           clusively licensed to a reference product  
19           sponsor with respect to the reference prod-  
20           uct and who has retained a right to assert  
21           the patent or participate in litigation con-  
22           cerning the patent may be provided the  
23           confidential information, provided that the  
24           representative informs the reference prod-  
25           uct sponsor and the subsection (k) appli-

1           cant of his or her agreement to be subject  
2           to the confidentiality provisions set forth in  
3           this paragraph, including those under  
4           clause (ii).

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

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

1 the subject of the application under subsection  
2 (k).

3 “(E) OWNERSHIP OF CONFIDENTIAL IN-  
4 FORMATION.—The confidential information dis-  
5 closed under this paragraph is, and shall re-  
6 main, the property of the subsection (k) appli-  
7 cant. By providing the confidential information  
8 pursuant to this paragraph, the subsection (k)  
9 applicant does not provide the reference product  
10 sponsor or the outside counsel any interest in or  
11 license to use the confidential information, for  
12 purposes other than those specified in subpara-  
13 graph (D).

14 “(F) EFFECT OF INFRINGEMENT AC-  
15 TION.—In the event that the reference product  
16 sponsor files a patent infringement suit, the use  
17 of confidential information shall continue to be  
18 governed by the terms of this paragraph until  
19 such time as a court enters a protective order  
20 regarding the information. Upon entry of such  
21 order, the subsection (k) applicant may redesign-  
22 nate confidential information in accordance  
23 with the terms of that order. No confidential in-  
24 formation shall be included in any publicly-  
25 available complaint or other pleading. In the

1 event that the reference product sponsor does  
2 not file an infringement action by the date spec-  
3 ified in paragraph (6), the reference product  
4 sponsor shall return or destroy all confidential  
5 information received under this paragraph, pro-  
6 vided that if the reference product sponsor opts  
7 to destroy such information, it will confirm de-  
8 struction in writing to the subsection (k) appli-  
9 cant.

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

12 “(i) as an admission by the subsection  
13 (k) applicant regarding the validity, en-  
14 forceability, or infringement of any patent;  
15 or

16 “(ii) as an agreement or admission by  
17 the subsection (k) applicant with respect to  
18 the competency, relevance, or materiality  
19 of any confidential information.

20 “(H) EFFECT OF VIOLATION.—The disclo-  
21 sure of any confidential information in violation  
22 of this paragraph shall be deemed to cause the  
23 subsection (k) applicant to suffer irreparable  
24 harm for which there is no adequate legal rem-  
25 edy and the court shall consider immediate in-



1           junctive relief to be an appropriate and nec-  
2           essary remedy for any violation or threatened  
3           violation of this paragraph.

4           “(2) SUBSECTION (k) APPLICATION INFORMA-  
5           TION.—Not later than 20 days after the Secretary  
6           notifies the subsection (k) applicant that the applica-  
7           tion has been accepted for review, the subsection (k)  
8           applicant—

9                   “(A) shall provide to the reference product  
10           sponsor a copy of the application submitted to  
11           the Secretary under subsection (k), and such  
12           other information that describes the process or  
13           processes used to manufacture the biological  
14           product that is the subject of such application;  
15           and

16                   “(B) may provide to the reference product  
17           sponsor additional information requested by or  
18           on behalf of the reference product sponsor.

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

20                   “(A) LIST BY REFERENCE PRODUCT SPON-  
21           SOR.—Not later than 60 days after the receipt  
22           of the application and information under para-  
23           graph (2), the reference product sponsor shall  
24           provide to the subsection (k) applicant—

1           “(i) a list of patents for which the ref-  
2           erence product sponsor believes a claim of  
3           patent infringement could reasonably be  
4           asserted by the reference product sponsor,  
5           or by a patent owner that has granted an  
6           exclusive license to the reference product  
7           sponsor with respect to the reference prod-  
8           uct, if a person not licensed by the ref-  
9           erence product sponsor engaged in the  
10          making, using, offering to sell, selling, or  
11          importing into the United States of the bi-  
12          ological product that is the subject of the  
13          subsection (k) application; and

14           “(ii) an identification of the patents  
15          on such list that the reference product  
16          sponsor would be prepared to license to the  
17          subsection (k) applicant.

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

22           “(i) may provide to the reference  
23          product sponsor a list of patents to which  
24          the subsection (k) applicant believes a  
25          claim of patent infringement could reason-

1 ably be asserted by the reference product  
2 sponsor if a person not licensed by the ref-  
3 erence product sponsor engaged in the  
4 making, using, offering to sell, selling, or  
5 importing into the United States of the bi-  
6 ological product that is the subject of the  
7 subsection (k) application;

8 “(ii) shall provide to the reference  
9 product sponsor, with respect to each pat-  
10 ent listed by the reference product sponsor  
11 under subparagraph (A) or listed by the  
12 subsection (k) applicant under clause (i)—

13 “(I) a detailed statement that de-  
14 scribes, on a claim by claim basis, the  
15 factual and legal basis of the opinion  
16 of the subsection (k) applicant that  
17 such patent is invalid, unenforceable,  
18 or will not be infringed by the com-  
19 mercial marketing of the biological  
20 product that is the subject of the sub-  
21 section (k) application; or

22 “(II) a statement that the sub-  
23 section (k) applicant does not intend  
24 to begin commercial marketing of the

1 biological product before the date that  
2 such patent expires; and

3 “(iii) shall provide to the reference  
4 product sponsor a response regarding each  
5 patent identified by the reference product  
6 sponsor under subparagraph (A)(ii).

7 “(C) DESCRIPTION BY REFERENCE PROD-  
8 UCT SPONSOR.—Not later than 60 days after  
9 receipt of the list and statement under subpara-  
10 graph (B), the reference product sponsor shall  
11 provide to the subsection (k) applicant a de-  
12 tailed statement that describes, with respect to  
13 each patent described in subparagraph  
14 (B)(ii)(I), on a claim by claim basis, the factual  
15 and legal basis of the opinion of the reference  
16 product sponsor that such patent will be in-  
17 fringed by the commercial marketing of the bio-  
18 logical product that is the subject of the sub-  
19 section (k) application and a response to the  
20 statement concerning validity and enforceability  
21 provided under subparagraph (B)(ii)(I).

22 “(4) PATENT RESOLUTION NEGOTIATIONS.—

23 “(A) IN GENERAL.—After receipt by the  
24 subsection (k) applicant of the statement under  
25 paragraph (3)(C), the reference product spon-

1           sor and the subsection (k) applicant shall en-  
2           gage in good faith negotiations to agree on  
3           which, if any, patents listed under paragraph  
4           (3) by the subsection (k) applicant or the ref-  
5           erence product sponsor shall be the subject of  
6           an action for patent infringement under para-  
7           graph (6).

8           “(B) FAILURE TO REACH AGREEMENT.—  
9           If, within 15 days of beginning negotiations  
10          under subparagraph (A), the subsection (k) ap-  
11          plicant and the reference product sponsor fail to  
12          agree on a final and complete list of which, if  
13          any, patents listed under paragraph (3) by the  
14          subsection (k) applicant or the reference prod-  
15          uct sponsor shall be the subject of an action for  
16          patent infringement under paragraph (6), the  
17          provisions of paragraph (5) shall apply to the  
18          parties.

19          “(5) PATENT RESOLUTION IF NO AGREE-  
20          MENT.—

21          “(A) NUMBER OF PATENTS.—The sub-  
22          section (k) applicant shall notify the reference  
23          product sponsor of the number of patents that  
24          such applicant will provide to the reference  
25          product sponsor under subparagraph (B)(i)(I).

1 “(B) EXCHANGE OF PATENT LISTS.—

2 “(i) IN GENERAL.—On a date agreed  
3 to by the subsection (k) applicant and the  
4 reference product sponsor, but in no case  
5 later than 5 days after the subsection (k)  
6 applicant notifies the reference product  
7 sponsor under subparagraph (A), the sub-  
8 section (k) applicant and the reference  
9 product sponsor shall simultaneously ex-  
10 change—

11 “(I) the list of patents that the  
12 subsection (k) applicant believes  
13 should be the subject of an action for  
14 patent infringement under paragraph  
15 (6); and

16 “(II) the list of patents, in ac-  
17 cordance with clause (ii), that the ref-  
18 erence product sponsor believes should  
19 be the subject of an action for patent  
20 infringement under paragraph (6).

21 “(ii) NUMBER OF PATENTS LISTED BY  
22 REFERENCE PRODUCT SPONSOR.—

23 “(I) IN GENERAL.—Subject to  
24 subclause (II), the number of patents  
25 listed by the reference product spon-

1                   sor under clause (i)(II) may not ex-  
2                   ceed the number of patents listed by  
3                   the subsection (k) applicant under  
4                   clause (i)(I).

5                   “(II) EXCEPTION.—If a sub-  
6                   section (k) applicant does not list any  
7                   patent under clause (i)(I), the ref-  
8                   erence product sponsor may list 1 pat-  
9                   ent under clause (i)(II).

10                   “(6) IMMEDIATE PATENT INFRINGEMENT AC-  
11                   TION.—

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

19                   “(B) ACTION IF NO AGREEMENT ON PAT-  
20                   ENT LIST.—If the provisions of paragraph (5)  
21                   apply to the parties as described in paragraph  
22                   (4)(B), not later than 30 days after the ex-  
23                   change of lists under paragraph (5)(B), the ref-  
24                   erence product sponsor shall bring an action for

1 patent infringement with respect to each patent  
2 that is included on such lists.

3 “(C) NOTIFICATION AND PUBLICATION OF  
4 COMPLAINT.—

5 “(i) NOTIFICATION TO SECRETARY.—

6 Not later than 30 days after the initial  
7 complaint is served to a subsection (k) ap-  
8 plicant in an action for patent infringe-  
9 ment described under this paragraph, the  
10 subsection (k) applicant shall provide the  
11 Secretary with notice and a copy of such  
12 complaint.

13 “(ii) PUBLICATION BY SECRETARY.—

14 The Secretary shall publish in the Federal  
15 Register notice of a complaint received  
16 under clause (i).

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

18 “(A) IN GENERAL.—Subparagraph (B)  
19 shall apply in the case of a patent—

20 “(i) that is issued to, or exclusively li-  
21 censed by, the reference product sponsor  
22 after the date that the reference product  
23 sponsor provided the list to the subsection  
24 (k) applicant under paragraph (3)(A); and



1                   “(ii) for which the reference product  
2                   sponsor reasonably believes that, due to  
3                   the issuance or licensing of such patent, a  
4                   claim of patent infringement could reason-  
5                   ably be asserted by the reference product  
6                   sponsor if a person not licensed by the ref-  
7                   erence product sponsor engaged in the  
8                   making, using, offering to sell, selling, or  
9                   importing into the United States of the bi-  
10                  ological product that is the subject of the  
11                  subsection (k) application.

12                  “(B) APPLICATION.—In the case of a pat-  
13                  ent described in subparagraph (A)—

14                         “(i) not later than 30 days after such  
15                         issuance or licensing, the reference product  
16                         sponsor shall provide to the subsection (k)  
17                         applicant a supplement to the list provided  
18                         by the reference product sponsor under  
19                         paragraph (3)(A) that includes such pat-  
20                         ent;

21                         “(ii) not later than 30 days after such  
22                         supplement is provided, the subsection (k)  
23                         applicant shall provide a statement to the  
24                         reference product sponsor in accordance  
25                         with paragraph (3)(B);

1           “(iii) not later than 30 days after re-  
2           ceipt of such statement, the reference  
3           product sponsor shall provide a statement  
4           to the subsection (k) applicant in accord-  
5           ance with paragraph (3)(C); and

6           “(iv) unless the subsection (k) appli-  
7           cant and the reference product sponsor  
8           agree pursuant to paragraph (4) that such  
9           a patent should be the subject of an action  
10          for patent infringement under subpara-  
11          graph (6)(A), such patent shall be subject  
12          to paragraph (8).

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

15           “(A) NOTICE OF COMMERCIAL MAR-  
16          KETING.—The subsection (k) applicant shall  
17          provide notice to the reference product sponsor  
18          not later than 180 days before the date of the  
19          first commercial marketing of the biological  
20          product licensed under subsection (k).

21           “(B) PRELIMINARY INJUNCTION.—After  
22          receiving the notice under subparagraph (A)  
23          and before such date of the first commercial  
24          marketing of such biological product, the ref-  
25          erence product sponsor may seek a preliminary

1 injunction prohibiting the subsection (k) appli-  
2 cant from engaging in the commercial manufac-  
3 ture or sale of such biological product until the  
4 court decides the issue of patent validity, en-  
5 forcement, and infringement with respect to any  
6 patent that is—

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

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

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

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

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

1           “(9) LIMITATION ON DECLARATORY JUDGMENT  
2           ACTION.—

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

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

1 list described in paragraph (3)(A), including as  
2 provided under paragraph (7).

3 “(C) SUBSECTION (k) APPLICATION NOT  
4 PROVIDED.—If a subsection (k) applicant fails  
5 to provide the application and information re-  
6 quired under paragraph (2)(A), the reference  
7 product sponsor, but not the subsection (k) ap-  
8 plicant, may bring an action under section 2201  
9 of title 28, United States Code, for a declara-  
10 tion of infringement, validity, or enforceability  
11 of any patent that claims the biological product  
12 or a use of the biological product.”.

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

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

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

19 (2) in paragraph (1), as so designated, by in-  
20 sserting “protein (except any chemically synthesized  
21 polypeptide),” after “allergenic product,”; and

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

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

1           “(A) that the biological product is highly  
2 similar to the reference product notwith-  
3 standing minor differences in clinically inactive  
4 components; and

5           “(B) there are no clinically meaningful dif-  
6 ferences between the biological product and the  
7 reference product in terms of the safety, purity,  
8 and potency of the product.

9           “(3) The term ‘interchangeable’ or ‘inter-  
10 changeability’, in reference to a biological product  
11 that is shown to meet the standards described in  
12 subsection (k)(4), means that the biological product  
13 may be substituted for the reference product without  
14 the intervention of the health care provider who pre-  
15 scribed the reference product.

16           “(4) The term ‘reference product’ means the  
17 single biological product licensed under subsection  
18 (a) against which a biological product is evaluated in  
19 an application submitted under subsection (k), in-  
20 cluding a biological product that is withdrawn from  
21 sale unless the Secretary—

22           “(A) has withdrawn or suspended the li-  
23 cense of such biological product for reasons of  
24 safety, purity, or potency;

1           “(B) has published a notice of opportunity  
2           for hearing to withdraw such license for such a  
3           reason; or

4           “(C) has determined that such biological  
5           product has been withdrawn from sale for such  
6           a reason.”.

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

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

11           (A) in paragraph (2)—

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

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

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

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

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

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

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

10 (B) in paragraph (4)—

11 (i) in subparagraph (B), by—

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

16 (II) striking “and” at the end;

17 (ii) in subparagraph (C), by—

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

20          “(n) APPLICATION TO BIOSIMILAR BIOLOGICAL  
21          PRODUCTS.—

22                 “(1) NON-INTERCHANGEABLE BIOSIMILAR BIO-  
23                 LOGICAL PRODUCT.—A biological product that is  
24                 biosimilar to a reference product under section 351  
25                 of the Public Health Service Act, and that the Sec-

1       retary has not determined to meet the standards de-  
2       scribed in subsection (k)(4) of such section for inter-  
3       changeability with the reference product, shall be  
4       subject to this section.

5               “(2) INTERCHANGEABLE BIOSIMILAR BIOLOGI-  
6       CAL PRODUCT.—A biological product that is inter-  
7       changeable with a reference product under section  
8       351 of the Public Health Service Act shall not be  
9       subject to this section.”.

10       (e) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-  
11       TION 505.—

12               (1) REQUIREMENT TO FOLLOW SECTION 351.—  
13       Except as provided in paragraph (2), an application  
14       for a biological product shall be submitted under  
15       section 351 of the Public Health Service Act (42  
16       U.S.C. 262) (as amended by this subtitle).

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

21                       (A) such biological product is in the same  
22                       product class as a biological product that is the  
23                       subject of an application approved under such  
24                       section 505 not later than the date of enact-  
25                       ment of this subtitle; and

1 (B) such application—

2 (i) has been submitted to the Sec-  
3 retary of Health and Human Services (re-  
4 ferred to in this subtitle as the “Sec-  
5 retary”) before the date of enactment of  
6 this subtitle; or

7 (ii) is submitted to the Secretary not  
8 later than the date that is 10 years after  
9 the date of enactment of this subtitle.

10 (3) LIMITATION.—Notwithstanding paragraph  
11 (2), an application for a biological product may not  
12 be submitted under section 505 of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 355) if there is  
14 another biological product licensed under subsection  
15 (a) of section 351 of the Public Health Service Act  
16 that could be a reference product with respect to  
17 such application (within the meaning of such section  
18 351) if such application were submitted under sub-  
19 section (k) of such section 351.

20 (4) DEEMED APPROVED UNDER SECTION  
21 351.—An approved application for a biological prod-  
22 uct under section 505 of the Federal Food, Drug,  
23 and Cosmetic Act (21 U.S.C. 355) shall be deemed  
24 to be a license for the biological product under such

1 section 351 on the date that is 10 years after the  
2 date of enactment of this subtitle.

3 (5) DEFINITIONS.—For purposes of this sub-  
4 section, the term “biological product” has the mean-  
5 ing given such term under section 351 of the Public  
6 Health Service Act (42 U.S.C. 262) (as amended by  
7 this subtitle).

8 (f) FOLLOW-ON BIOLOGICS USER FEES.—

9 (1) DEVELOPMENT OF USER FEES FOR BIO-  
10 SIMILAR BIOLOGICAL PRODUCTS.—

11 (A) IN GENERAL.—Beginning not later  
12 than October 1, 2010, the Secretary shall de-  
13 velop recommendations to present to Congress  
14 with respect to the goals, and plans for meeting  
15 the goals, for the process for the review of bio-  
16 similar biological product applications sub-  
17 mitted under section 351(k) of the Public  
18 Health Service Act (as added by this subtitle)  
19 for the first 5 fiscal years after fiscal year  
20 2012. In developing such recommendations, the  
21 Secretary shall consult with—

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

1 (ii) the Committee on Energy and  
2 Commerce of the House of Representa-  
3 tives;

4 (iii) scientific and academic experts;

5 (iv) health care professionals;

6 (v) representatives of patient and con-  
7 sumer advocacy groups; and

8 (vi) the regulated industry.

9 (B) PUBLIC REVIEW OF RECOMMENDA-  
10 TIONS.—After negotiations with the regulated  
11 industry, the Secretary shall—

12 (i) present the recommendations de-  
13 veloped under subparagraph (A) to the  
14 Congressional committees specified in such  
15 subparagraph;

16 (ii) publish such recommendations in  
17 the Federal Register;

18 (iii) provide for a period of 30 days  
19 for the public to provide written comments  
20 on such recommendations;

21 (iv) hold a meeting at which the pub-  
22 lic may present its views on such rec-  
23 ommendations; and

1 (v) after consideration of such public  
2 views and comments, revise such rec-  
3 ommendations as necessary.

4 (C) TRANSMITTAL OF RECOMMENDA-  
5 TIONS.—Not later than January 15, 2012, the  
6 Secretary shall transmit to Congress the revised  
7 recommendations under subparagraph (B), a  
8 summary of the views and comments received  
9 under such subparagraph, and any changes  
10 made to the recommendations in response to  
11 such views and comments.

12 (2) ESTABLISHMENT OF USER FEE PRO-  
13 GRAM.—It is the sense of the Senate that, based on  
14 the recommendations transmitted to Congress by the  
15 Secretary pursuant to paragraph (1)(C), Congress  
16 should authorize a program, effective on October 1,  
17 2012, for the collection of user fees relating to the  
18 submission of biosimilar biological product applica-  
19 tions under section 351(k) of the Public Health  
20 Service Act (as added by this subtitle).

21 (3) TRANSITIONAL PROVISIONS FOR USER FEES  
22 FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

23 (A) APPLICATION OF THE PRESCRIPTION  
24 DRUG USER FEE PROVISIONS.—Section  
25 735(1)(B) of the Federal Food, Drug, and Cos-



1           metic Act (21 U.S.C. 379g(1)(B)) is amended  
2           by striking “section 351” and inserting “sub-  
3           section (a) or (k) of section 351”.

4                   (B) EVALUATION OF COSTS OF REVIEWING  
5           BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-  
6           TIONS.—During the period beginning on the  
7           date of enactment of this subtitle and ending on  
8           October 1, 2010, the Secretary shall collect and  
9           evaluate data regarding the costs of reviewing  
10          applications for biological products submitted  
11          under section 351(k) of the Public Health Serv-  
12          ice Act (as added by this subtitle) during such  
13          period.

14                   (C) AUDIT.—

15                   (i) IN GENERAL.—On the date that is  
16                  2 years after first receiving a user fee ap-  
17                  plicable to an application for a biological  
18                  product under section 351(k) of the Public  
19                  Health Service Act (as added by this sub-  
20                  title), and on a biennial basis thereafter  
21                  until October 1, 2013, the Secretary shall  
22                  perform an audit of the costs of reviewing  
23                  such applications under such section  
24                  351(k). Such an audit shall compare—

1 (I) the costs of reviewing such  
2 applications under such section  
3 351(k) to the amount of the user fee  
4 applicable to such applications; and

5 (II)(aa) such ratio determined  
6 under subclause (I); to

7 (bb) the ratio of the costs of re-  
8 viewing applications for biological  
9 products under section 351(a) of such  
10 Act (as amended by this subtitle) to  
11 the amount of the user fee applicable  
12 to such applications under such sec-  
13 tion 351(a).

14 (ii) ALTERATION OF USER FEE.—If  
15 the audit performed under clause (i) indi-  
16 cates that the ratios compared under sub-  
17 clause (II) of such clause differ by more  
18 than 5 percent, then the Secretary shall  
19 alter the user fee applicable to applications  
20 submitted under such section 351(k) to  
21 more appropriately account for the costs of  
22 reviewing such applications.

23 (iii) ACCOUNTING STANDARDS.—The  
24 Secretary shall perform an audit under  
25 clause (i) in conformance with the account-

1 ing principles, standards, and requirements  
2 prescribed by the Comptroller General of  
3 the United States under section 3511 of  
4 title 31, United State Code, to ensure the  
5 validity of any potential variability.

6 (4) AUTHORIZATION OF APPROPRIATIONS.—  
7 There is authorized to be appropriated to carry out  
8 this subsection such sums as may be necessary for  
9 each of fiscal years 2010 through 2012.

10 (g) ORPHAN PRODUCTS.—If a reference product, as  
11 defined in section 351 of the Public Health Service Act  
12 (42 U.S.C. 262) (as amended by this subtitle) has been  
13 designated under section 526 of the Federal Food, Drug,  
14 and Cosmetic Act (21 U.S.C. 360bb) for a rare disease  
15 or condition, a biological product seeking approval for  
16 such disease or condition under subsection (k) of such sec-  
17 tion 351 as biosimilar to, or interchangeable with, such  
18 reference product may be licensed by the Secretary only  
19 after the expiration for such reference product of the later  
20 of—

21 (1) the 7-year period described in section  
22 527(a) of the Federal Food, Drug, and Cosmetic Act  
23 (21 U.S.C. 360cc(a)); and

24 (2) the 9-year described in subsection (k)(7) of  
25 such section 351.

1 **SEC. 603. PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS.**

2 (a) IN GENERAL.—Section 351 of the Public Health  
3 Service Act (42 U.S.C. 262), as amended by section 602,  
4 is further amended by adding at the end the following:

5 “(m) PEDIATRIC STUDIES.—

6 “(1) APPLICATION OF CERTAIN PROVISIONS.—

7 The provisions of subsections (a), (d), (e), (f), (i),  
8 (j), (k), (l), (p), and (q) of section 505A of the Fed-  
9 eral Food, Drug, and Cosmetic Act shall apply with  
10 respect to the extension of a period under para-  
11 graphs (2) and (3) to the same extent and in the  
12 same manner as such provisions apply with respect  
13 to the extension of a period under subsection (b) or  
14 (c) of section 505A of the Federal Food, Drug, and  
15 Cosmetic Act.

16 “(2) MARKET EXCLUSIVITY FOR NEW BIOLOGI-  
17 CAL PRODUCTS.—If, prior to approval of an applica-  
18 tion that is submitted under subsection (a), the Sec-  
19 retary determines that information relating to the  
20 use of a new biological product in the pediatric pop-  
21 ulation may produce health benefits in that popu-  
22 lation, the Secretary makes a written request for pe-  
23 diatric studies (which shall include a timeframe for  
24 completing such studies), the applicant agrees to the  
25 request, such studies are completed using appro-  
26 priate formulations for each age group for which the

1 study is requested within any such timeframe, and  
2 the reports thereof are submitted and accepted in  
3 accordance with section 505A(d)(3) of the Federal  
4 Food, Drug, and Cosmetic Act—

5 “(A) the periods for such biological prod-  
6 uct referred to in subsection (k)(7) are deemed  
7 to be 2 years and 6 months rather than 2 years  
8 and 9 years and 6 months rather than 9 years;  
9 and

10 “(B) if the biological product is designated  
11 under section 526 for a rare disease or condi-  
12 tion, the period for such biological product re-  
13 ferred to in section 527(a) is deemed to be 7  
14 years and 6 months rather than 7 years.

15 “(3) MARKET EXCLUSIVITY FOR ALREADY-MAR-  
16 KETED BIOLOGICAL PRODUCTS.—If the Secretary  
17 determines that information relating to the use of a  
18 licensed biological product in the pediatric popu-  
19 lation may produce health benefits in that popu-  
20 lation and makes a written request to the holder of  
21 an approved application under subsection (a) for pe-  
22 diatric studies (which shall include a timeframe for  
23 completing such studies), the holder agrees to the  
24 request, such studies are completed using appro-  
25 priate formulations for each age group for which the

1 study is requested within any such timeframe, and  
2 the reports thereof are submitted and accepted in  
3 accordance with section 505A(d)(3) of the Federal  
4 Food, Drug, and Cosmetic Act—

5 “(A) the periods for such biological prod-  
6 uct referred to in subsection (k)(7) are deemed  
7 to be 2 years and 6 months rather than 2 years  
8 and 9 years and 6 months rather than 9 years;  
9 and

10 “(B) if the biological product is designated  
11 under section 526 for a rare disease or condi-  
12 tion, the period for such biological product re-  
13 ferred to in section 527(a) is deemed to be 7  
14 years and 6 months rather than 7 years.

15 “(4) EXCEPTION.—The Secretary shall not ex-  
16 tend a period referred to in paragraph (2)(A),  
17 (2)(B), (3)(A), or (3)(B) if the determination under  
18 section 505A(d)(3) is made later than 9 months  
19 prior to the expiration of such period.”.

20 (b) STUDIES REGARDING PEDIATRIC RESEARCH.—

21 (1) PROGRAM FOR PEDIATRIC STUDY OF  
22 DRUGS.—Subsection (a)(1) of section 409I of the  
23 Public Health Service Act (42 U.S.C. 284m) is  
24 amended by inserting “, biological products,” after  
25 “including drugs”.

1           (2) INSTITUTE OF MEDICINE STUDY.—Section  
2           505A(p) of the Federal Food, Drug, and Cosmetic  
3           Act (21 U.S.C. 355b(p)) is amended by striking  
4           paragraphs (4) and (5) and inserting the following:

5           “(4) review and assess the number and impor-  
6           tance of biological products for children that are  
7           being tested as a result of the amendments made by  
8           the Biologics Price Competition and Innovation Act  
9           of 2009 and the importance for children, health care  
10          providers, parents, and others of labeling changes  
11          made as a result of such testing;

12          “(5) review and assess the number, importance,  
13          and prioritization of any biological products that are  
14          not being tested for pediatric use; and

15          “(6) offer recommendations for ensuring pedi-  
16          atric testing of biological products, including consid-  
17          eration of any incentives, such as those provided  
18          under this section or section 351(m) of the Public  
19          Health Service Act.”.