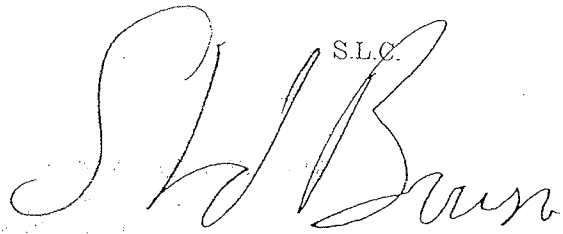


S.L.C.


AMENDMENT NO. 200

Calendar No. _____

Purpose: To establish a pathway for the licensure of bio-similar biological products and to promote ~~innovation~~ 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

Sen. Brown

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 (1)(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 (1)(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 (1)(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 (1)(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 7-year period beginning
22 on such product’s approval date; or

23 “(II) such period, as extended
24 under subparagraph (D).

1 “(ii) 3-YEAR PERIOD.—If an applica-
2 tion under this subsection refers to a bio-
3 logical product described in subparagraph
4 (C), the Secretary may not approve such
5 application for the conditions of approval
6 of such product before the expiration of—

7 “(I) the 3-year period beginning
8 on such product’s approval date; or

9 “(II) such period, as extended
10 under subparagraph (D).

11 “(B) NO MAJOR SUBSTANCE PREVIOUSLY
12 APPROVED.—

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

15 “(I) an application is submitted
16 for such product under subsection (a);

17 “(II) no major substance of the
18 product, nor any highly similar major
19 substance, has been approved in any
20 other application under subsection (a);

21 “(III) the application submitted
22 for such product is approved after the
23 date of the enactment of this sub-
24 section; and

1 “(IV) the application submitted
2 for such product could not and did
3 not rely on any clinical safety, purity,
4 or potency study in any ~~other~~ applica-
5 tion approved under this section or
6 any clinical safety or effectiveness
7 study in any application approved
8 under section 505 of the Federal
9 Food, Drug, and Cosmetic Act.

10 “(i) EXCLUSIONS.—Biological prod-
11 ucts not described in clause (i) include the
12 following:

13 “(I) Protein biological products
14 that differ in structure solely due to
15 post-translational events, infidelity of
16 translation or transcription, or minor
17 differences in amino acid sequence.

18 “(II) Polysaccharide biological
19 products with similar saccharide re-
20 peating units, even if the number of
21 units differ and even if there are dif-
22 ferences in post-polymerization modi-
23 fications.

24 “(III) Glycosylated protein prod-
25 ucts that differ in structure solely due

1 to post-translational events, infidelity
2 of translation or transcription, or
3 minor differences in amino acid se-
4 quence, and if they had similar sac-
5 charide repeating units, ~~even~~ if the
6 number of units differ and even if
7 there were differences in post-polym-
8 erization modifications.

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 “(V) Closely related, complex
16 partly definable biological products
17 with similar therapeutic intent, such
18 as live viral products for the same in-
19 dication.

20 The Secretary may by regulation identify addi-
21 tional biological products not described in
22 clause (i).

23 “(C) MAJOR SUBSTANCE PREVIOUSLY AP-
24 PROVED.—A biological product is described in
25 this subparagraph if—

1 “(i) an application is submitted for
2 such product under subsection (a);

3 “(ii) such product includes a major
4 substance that has been approved in an-
5 other application under subsection (a), or
6 any highly similar major substance;

7 “(iii) the application submitted for
8 such product is approved after the date of
9 the enactment of this subsection;

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

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

23 “(D) BONUS EXCLUSIVITY FOR SIGNIFI-
24 CANT INNOVATION.—

1 “(i) IN GENERAL.—If a supplement to
2 an application approved under subsection
3 (a) is approved no later than 1 year before
4 the expiration of a period to which the ap-
5 plicant is entitled under subparagraph (A),
6 the period described in subparagraph (A)
7 shall, except as provided in clause (ii), be
8 extended by 6 months if—

9 “(I) the supplement contains re-
10 ports of new clinical investigations
11 (other than pharmacokinetic or
12 pharmacodynamic studies) essential to
13 the approval of the supplement and
14 conducted or sponsored by the person
15 submitting the supplement; and

16 “(II) the product that is the sub-
17 ject of the supplement provides a sig-
18 nificant therapeutic advance, which
19 may include demonstration of safety,
20 purity, and potency for a significant
21 new indication or subpopulation, other
22 than a pediatric subpopulation.

23 “(ii) ADJUSTMENT.—Any period of
24 market exclusivity extended under sub-
25 clause (I) or (II) of clause (i) for a biologi-

1 cal product shall be reduced by 90 days if
2 the organization designated under subpara-
3 graph (E) notifies the Secretary that, with
4 respect to any major substance contained
5 in the biological product, the combined an-
6 nual gross sales in the United States for
7 all biological products—

8 “(I) containing the major sub-
9 stance; and

10 “(II) owned or marketed by the
11 applicant or its affiliates;
12 exceeded \$1,000,000,000 in the calendar
13 year preceding approval of the supplement
14 involved.

15 “(iii) LIMITATION.—Only one exten-
16 sion under this subparagraph may be
17 granted for any biological product.

18 “(E) DESIGNATIONS.—The Secretary shall
19 designate an organization other than the Food
20 and Drug Administration to make the deter-
21 mination of combined annual gross sales de-
22 scribed in subparagraph (D)(ii). Prior to desig-
23 nating such organization, the Secretary shall
24 determine that such organization is independent
25 and is qualified to evaluate the sales of pharma-

1 ceutical products. The Secretary shall re-evalu-
2 ate the designation of such organization once
3 every 3 years.

4 “(8) GUIDANCE DOCUMENTS.—

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

13 “(B) PUBLIC COMMENT.—

14 “(i) IN GENERAL.—The Secretary
15 shall provide the public an opportunity to
16 comment on any proposed guidance issued
17 under subparagraph (A) before issuing
18 final guidance.

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

24 “(C) NO REQUIREMENT FOR APPLICATION
25 REVIEW OR ACTION.—The issuance (or non-

1 issuance) of guidance under subparagraph (A)
2 shall not preclude the review of, or action on,
3 an application submitted under this subsection.

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

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

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

17 “(E) CERTAIN PRODUCT CLASSES.—

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

1 under this subsection for such product or
2 product class.

3 “(ii) MODIFICATION OR REVERSAL.—
4 The Secretary may issue a subsequent
5 guidance document under subparagraph
6 (A) to modify or reverse a guidance docu-
7 ment under clause (i).

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

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

22 “(l) PATENTS.—

23 “(1) CONFIDENTIAL ACCESS TO SUBSECTION
24 (k) APPLICATION.—

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

11 “(B) IN GENERAL.—

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

1 “(ii) RECIPIENTS OF INFORMATION.—

2 The persons described in this clause are
3 the following:

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

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

22 “(iii) PATENT OWNER ACCESS.—A
23 representative of the owner of a patent ex-
24 clusively licensed to a reference product
25 sponsor with respect to the reference prod-

1 uct and who has retained a right to assert
2 the patent or participate in litigation con-
3 cerning the patent may be provided the
4 confidential information, provided that the
5 representative informs the reference prod-
6 uct sponsor and the subsection (k) appli-
7 cant of his or her agreement to be subject
8 to the confidentiality provisions set forth in
9 this paragraph, including those under
10 clause (ii).

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

21 “(D) USE OF CONFIDENTIAL INFORMA-
22 TION.—Confidential information shall be used
23 for the sole and exclusive purpose of deter-
24 mining, with respect to each patent assigned to
25 or exclusively licensed by the reference product

1 sponsor, whether a claim of patent infringement
2 could reasonably be asserted if the subsection
3 (k) applicant engaged in the manufacture, use,
4 offering for sale, sale, or importation into the
5 United States of the biological product that is
6 the subject of the application under subsection
7 (k).

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

19 “(F) EFFECT OF INFRINGEMENT AC-
20 TION.—In the event that the reference product
21 sponsor files a patent infringement suit, the use
22 of confidential information shall continue to be
23 governed by the terms of this paragraph until
24 such time as a court enters a protective order
25 regarding the information. Upon entry of such

1 order, the subsection (k) applicant may redesignig-
2 nate confidential information in accordance
3 with the terms of that order. No confidential in-
4 formation shall be included in ~~any~~ publicly-
5 available complaint or other pleading. In the
6 event that the reference product sponsor does
7 not file an infringement action by the date spec-
8 ified in paragraph (6), the reference product
9 sponsor shall return or destroy all confidential
10 information received under this paragraph, pro-
11 vided that if the reference product sponsor opts
12 to destroy such information, it will confirm de-
13 struction in writing to the subsection (k) appli-
14 cant.

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

17 “(i) as an admission by the subsection
18 (k) applicant regarding the validity, en-
19 forceability, or infringement of any patent;
20 or

21 “(ii) as an agreement or admission by
22 the subsection (k) applicant with respect to
23 the competency, relevance, or materiality
24 of any confidential information.

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

10 “(2) SUBSECTION (k) APPLICATION INFORMA-
11 TION.—Not later than 20 days after the Secretary
12 notifies the subsection (k) applicant that the applica-
13 tion has been accepted for review, the subsection (k)
14 applicant—

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

22 “(B) may provide to the reference product
23 sponsor additional information requested by or
24 on behalf of the reference product sponsor.

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

1 days after receipt of the list under subpara-
2 graph (A), the subsection (k) applicant—

3 “(i) may provide to the reference
4 product sponsor a list of patents to which
5 the subsection (k) applicant believes a
6 claim of patent infringement could reason-
7 ably be asserted by the reference product
8 sponsor 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;

14 “(ii) shall provide to the reference
15 product sponsor, with respect to each pat-
16 ent listed by the reference product sponsor
17 under subparagraph (A) or listed by the
18 subsection (k) applicant under clause (i)—

19 “(I) a detailed statement that de-
20 scribes, on a claim by claim basis, the
21 factual and legal basis of the opinion
22 of the subsection (k) applicant that
23 such patent is invalid, unenforceable,
24 or will not be infringed by the com-
25 mercial marketing of the biological

1 product that is the subject of the sub-
2 section (k) application; or

3 “(II) a statement that the sub-
4 section (k) applicant does not intend
5 to begin commercial marketing of the
6 biological product before the date that
7 such patent expires; and

8 “(iii) shall provide to the reference
9 product sponsor a response regarding each
10 patent identified by the reference product
11 sponsor under subparagraph (A)(ii).

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

1 statement concerning validity and enforceability
2 provided under subparagraph (B)(ii)(I).

3 “(4) PATENT RESOLUTION NEGOTIATIONS.—

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

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

1 “(5) PATENT RESOLUTION IF NO AGREE-
2 MENT.—

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

8 “(B) EXCHANGE OF PATENT LISTS.—

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

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

23 “(II) the list of patents, in ac-
24 cordance with clause (ii), that the ref-
25 erence product sponsor believes should

1 be the subject of an action for patent
2 infringement under paragraph (6).

3 “(ii) NUMBER OF PATENTS LISTED BY
4 REFERENCE PRODUCT SPONSOR.—

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

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

17 “(6) IMMEDIATE PATENT INFRINGEMENT AC-
18 TION.—

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

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

9 “(C) NOTIFICATION AND PUBLICATION OF
10 COMPLAINT.—

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

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

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

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

1 “(i) that is issued to, or exclusively li-
2 censed by, the reference product sponsor
3 after the date that the reference product
4 sponsor provided the list to the subsection
5 (k) applicant under paragraph (3)~~(A)~~; and

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

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

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

1 “(ii) not later than 30 days after such
2 supplement is provided, the subsection (k)
3 applicant shall provide a statement to the
4 reference product sponsor in accordance
5 with paragraph (3)(B);

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

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

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

20 “(A) NOTICE OF COMMERCIAL MAR-
21 KETING.—The subsection (k) applicant shall
22 provide notice to the reference product sponsor
23 not later than 180 days before the date of the
24 first commercial marketing of the biological
25 product licensed under subsection (k).

1 “(B) PRELIMINARY INJUNCTION.—After
2 receiving the notice under subparagraph (A)
3 and before such date of the first commercial
4 marketing of such biological product, the ref-
5 erence product sponsor may seek a preliminary
6 injunction prohibiting the subsection (k) appli-
7 cant from engaging in the commercial manufac-
8 ture or sale of such biological product until the
9 court decides the issue of patent validity, en-
10 forcement, and infringement with respect to any
11 patent that is—

12 “(i) included in the list provided by
13 the reference product sponsor under para-
14 graph (3)(A) or in the list provided by the
15 subsection (k) applicant under paragraph
16 (3)(B); and

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

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

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

22 “(C) REASONABLE COOPERATION.—If the
23 reference product sponsor has sought a prelimi-
24 nary injunction under subparagraph (B), the
25 reference product sponsor and the subsection

1 (k) applicant shall reasonably cooperate to ex-
2 pedite such further discovery as is needed in
3 connection with the preliminary injunction mo-
4 tion.

5 “(9) LIMITATION ON DECLARATORY JUDGMENT
6 ACTION.—

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

18 “(B) SUBSEQUENT FAILURE TO ACT BY
19 SUBSECTION (k) APPLICANT.—If a subsection
20 (k) applicant fails to complete an action re-
21 quired of the subsection (k) applicant under
22 paragraph (3)(B)(ii), paragraph (5), paragraph
23 (6)(C)(i), paragraph (7), or paragraph (8)(A),
24 the reference product sponsor, but not the sub-
25 section (k) applicant, may bring an action

1 under section 2201 of title 28, United States
2 Code, for a declaration of infringement, validity,
3 or enforceability of any patent included in the
4 list described in paragraph (3)(A), including as
5 provided under paragraph (7).

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

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

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

20 “In this section:

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

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

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

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

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

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

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

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

1 “(A) has withdrawn or suspended the li-
2 cense of such biological product for reasons of
3 safety, purity, or potency;

4 “(B) has published a notice of opportunity
5 for hearing to withdraw such license ~~for~~ such a
6 reason; or

7 “(C) has determined that such biological
8 product has been withdrawn from sale for such
9 a reason.”.

10 (c) 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(l)(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(l)(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 (II) 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 injunc-
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(d)(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 lic 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 or exclusive licensee of a patent that
22 should have been included in the list described in section
23 351(1)(3)(A) of the Public Health Service Act, including
24 as provided under section 351(1)(7) of such Act for a bio-
25 logical product, but was not timely included in such list,

1 may not bring an action under this section for infringe-
2 ment of the patent 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) PEDIATRIC ASSESSMENTS.—Section 505B
19 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 355c) is amended by adding at the end the
21 following:

22 “(n) APPLICATION TO BIOSIMILAR BIOLOGICAL
23 PRODUCTS.—

24 “(1) NON-INTERCHANGEABLE BIOSIMILAR BIO-
25 LOGICAL PRODUCT.—A biological product that is

1 biosimilar to a reference product under section 351
2 of the Public Health Service Act, and that the Sec-
3 retary has not determined to meet the standards de-
4 scribed in subsection (k)(4) of such section for inter-
5 changeability with the reference product, shall be
6 subject to this section.

7 “(2) INTERCHANGEABLE BIOSIMILAR BIOLOGI-
8 CAL PRODUCT.—A biological product that is inter-
9 changeable with a reference product under section
10 351 of the Public Health Service Act shall not be
11 subject to this section.”

12 (e) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-
13 TION 505.—

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

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

23 (A) such biological product is in the same
24 product class as a biological product that is the
25 subject of an application approved under such

1 section 505 not later than the date of enact-
2 ment of this subtitle; and

3 (B) such application—

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

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

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

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

1 to be a license for the biological product under such
2 section 351 on the date that is 10 years after the
3 date of enactment of this subtitle.

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

9 (f) FOLLOW-ON BIOLOGICS USER FEES.—

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

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

23 (i) the Committee on Health, Edu-
24 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 metac 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 7-
20 year period described in section 527(a) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) and
22 in subsection (k)(7) of 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 3 years and 6 months rather than 3 years
8 and 7 years and 6 months rather than 7 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 3 years and 6 months rather than 3 years
8 and 7 years and 6 months rather than 7 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.”.