

Calendar No. 1127110TH CONGRESS
2^D SESSION**S. 1695**

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

IN THE SENATE OF THE UNITED STATES

JUNE 26, 2007

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

NOVEMBER 19, 2008

Reported by Mr. KENNEDY, with an amendment

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

A BILL

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

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

1 **SECTION 1. SHORT TITLE.**

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

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

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

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

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

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

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

18 “(2) **CONTENT.**—

19 “(A) **IN GENERAL.**—

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

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

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

7 “(bb) animal studies; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 or

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

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

24 “(A) the biological product—

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

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

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

13 “(5) GENERAL RULES.—

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

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

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

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

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

23 “(B) 18 months after—

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

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

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

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

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

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

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

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

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

14 ~~“(8) GUIDANCE DOCUMENTS.—~~

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

24 ~~“(B) PUBLIC COMMENT.—~~

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

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

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

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

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

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

5 “(E) CERTAIN PRODUCT CLASSES.—

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

15 “(ii) MODIFICATION OR REVERSAL.—

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

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

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

3 “(1) PATENTS.—

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

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

16 “(B) IN GENERAL.—

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

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

5 “(ii) RECIPIENTS OF INFORMATION.—

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

8 “(I) OUTSIDE COUNSEL.—One or

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

18 “(II) IN-HOUSE COUNSEL.—One

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 “(4) PATENT RESOLUTION NEGOTIATIONS.—

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

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

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

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

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

16 “(B) EXCHANGE OF PATENT LISTS.—

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

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

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

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

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

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

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

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

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

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

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

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

3 “(ii) PUBLICATION BY SECRETARY.—

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

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

8 In the case of a patent that—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 “In this section:

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

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

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

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

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

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

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

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

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

14 (A) in paragraph (2)—

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

16 “or” at the end;

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

18 “or” at the end; and

19 (iii) by inserting after subparagraph

20 (B) the following:

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

1 application seeking approval of a biological product,
2 or

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

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

14 (B) in paragraph (4)—

15 (i) in subparagraph (B), by—

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

20 (II) striking “and” at the end;

21 (ii) in subparagraph (C), by—

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

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

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

5 “(D) the court shall order a permanent 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(l)(6) of such Act, and the biological prod-
15 uct has not yet been approved because of section
16 351(k)(7) of such Act.”; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 (1) REQUIREMENT TO FOLLOW SECTION 351.—

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

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

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

19 (B) such application—

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

24 or

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 (C) AUDIT.—

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

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

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

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

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

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

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

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

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

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

11 (2) SPECIAL RESERVE FUND.—

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

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

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

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

3 **SECTION 1. SHORT TITLE.**

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

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

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

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

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

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

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

20 “(2) *CONTENT.*—

21 “(A) *IN GENERAL.*—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 “(A) the biological product—

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

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

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

16 “(5) GENERAL RULES.—

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

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

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

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

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

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

25 “(B) *18 months after—*

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

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

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

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

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

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

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

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

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

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

22 “(8) *GUIDANCE DOCUMENTS.*—

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

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

6 “(B) PUBLIC COMMENT.—

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

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

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

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

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

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

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

11 “(E) *CERTAIN PRODUCT CLASSES.—*

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

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

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

9 “(l) *PATENTS.—*

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

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

21 “(B) *IN GENERAL.—*

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

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

9 “(ii) *RECIPIENTS OF INFORMATION.*—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 *commercial marketing of the biological product*
2 *that is the subject of the subsection (k) applica-*
3 *tion and a response to the statement concerning*
4 *validity and enforceability provided under sub-*
5 *paragraph (B)(ii)(I).*

6 “(4) *PATENT RESOLUTION NEGOTIATIONS.*—

7 “(A) *IN GENERAL.*—*After receipt by the*
8 *subsection (k) applicant of the statement under*
9 *paragraph (3)(C), the reference product sponsor*
10 *and the subsection (k) applicant shall engage in*
11 *good faith negotiations to agree on which, if any,*
12 *patents listed under paragraph (3) by the sub-*
13 *section (k) applicant or the reference product*
14 *sponsor shall be the subject of an action for pat-*
15 *ent infringement under paragraph (6).*

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

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

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

7 “(B) *EXCHANGE OF PATENT LISTS.*—

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

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

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

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

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

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

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

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

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

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

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

9 “(i) NOTIFICATION TO SECRETARY.—

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

16 “(ii) PUBLICATION BY SECRETARY.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 (A) *in paragraph (2)—*

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

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

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

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

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

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

6 (B) in paragraph (4)—

7 (i) in subparagraph (B), by—

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

12 (II) striking “and” at the end;

13 (ii) in subparagraph (C), by—

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

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

20 (iii) by inserting after subparagraph

21 (C) the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 “(i) *NEW ACTIVE INGREDIENT.*—

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

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

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

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

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

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

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

19 *(B) such application—*

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

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

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

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

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

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

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

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

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

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

19 (iii) *scientific and academic experts;*

20 (iv) *health care professionals;*

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

23 (vi) *the regulated industry.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 (C) *AUDIT.—*

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

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

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

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

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

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

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

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

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

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

8 (2) *SPECIAL RESERVE FUND.*—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Calendar No. 1127

110TH CONGRESS
2^D SESSION

S. 1695

A BILL

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

NOVEMBER 19, 2008

Reported with an amendment