~~SUBCOMMITTEE ON ENERGY AND ENVIRONMENT~~ -- 111TH CONGRESS
ROLL CALL VOTE #

BILL: H.R. 3200, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: Amendment by Rep. Eshoo.

DISPOSITION: FAILED/AGREED TO, by a roll call vote of 47 yeas to 11 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		✓		Mr. Barton	✓		
Mr. Dingell		✓		Mr. Hall	✓		
Mr. Markey	✓			Mr. Upton	✓		
Mr. Boucher	✓			Mr. Stearns	✓		
Mr. Pallone		✓		Mr. Deal		✓	
Mr. Gordon	✓			Mr. Whitfield	✓		
Mr. Rush	✓			Mr. Shimkus	✓		
Ms. Eshoo	✓			Mr. Shadegg	✓		
Mr. Stupak	✓			Mr. Blunt			
Mr. Engel	✓			Mr. Buyer	✓		
Mr. Green	✓			Mr. Radanovich	✓		
Ms. DeGette	✓			Mr. Pitts	✓		
Ms. Capps		✓		Ms. Bono Mack	✓		
Mr. Doyle	✓			Mr. Walden	✓		
Ms. Harman	✓			Mr. Terry	✓		
Ms. Schakowsky		✓		Mr. Rogers	✓		
Mr. Gonzalez	✓			Ms. Myrick	✓		
Mr. Inslee	✓			Mr. Sullivan	✓		
Ms. Baldwin	✓			Mr. Murphy (PA)	✓		
Mr. Ross	✓			Mr. Burgess	✓		
Mr. Weiner		✓		Ms. Blackburn	✓		
Mr. Matheson	✓			Mr. Gingrey	✓		
Mr. Butterfield	✓			Mr. Scalise	✓		
Mr. Melancon	✓				21	1	
Mr. Barrow	✓						
Mr. Hill	✓						
Ms. Matsui	✓						
Ms. Christensen	✓						
Ms. Castor		✓					
Mr. Sarbanes		✓					
Mr. Murphy (CT)	✓						
Mr. Space	✓						
Mr. McNerney	✓						
Ms. Sutton		✓					
Mr. Braley	✓						
Mr. Welch		✓					

Current as of 1/13/09 26 10

Monday 5:39pm
C

AMENDMENT

OFFERED BY MS. ESHOO OF CALIFORNIA, MR. INSLEE OF WASHINGTON, AND MR. BARTON OF TEXAS

At the end of title V of division C, add the following:

Subtitle ____—Pathway for Biosimilars

SEC. ____. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting "under this subsection or subsection (k)" after "biologics license"; and

(2) by adding at the end the following:

"(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

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

"(2) CONTENT.—

"(A) IN GENERAL.—

1 "(i) REQUIRED INFORMATION.—An
2 application submitted under this subsection
3 shall include information demonstrating
4 that—
5 "(I) the biological product is bio-
6 similar to a reference product based
7 upon data derived from—
8 "(aa) analytical studies that
9 demonstrate that the biological
10 product is highly similar to the
11 reference product notwith-
12 standing minor differences in
13 clinically inactive components;
14 "(bb) animal studies (includ-
15 ing the assessment of toxicity);
16 and
17 "(cc) a clinical study or
18 studies (including the assessment
19 of immunogenicity and phar-
20 macokinetics or
21 pharmacodynamics) that are suf-
22 ficient to demonstrate safety, pu-
23 rity, and potency in 1 or more
24 appropriate conditions of use for
25 which the reference product is li-

1 censed and intended to be used
2 and for which licensure is sought
3 for the biological product;
4 "(II) the biological product and
5 reference product utilize the same
6 mechanism or mechanisms of action
7 for the condition or conditions of use
8 prescribed, recommended, or sug-
9 gested in the proposed labeling, but
10 only to the extent the mechanism or
11 mechanisms of action are known for
12 the reference product;
13 "(III) the condition or conditions
14 of use prescribed, recommended, or
15 suggested in the labeling proposed for
16 the biological product have been pre-
17 viously approved for the reference
18 product;
19 "(IV) the route of administra-
20 tion, the dosage form, and the
21 strength of the biological product are
22 the same as those of the reference
23 product; and
24 "(V) the facility in which the bio-
25 logical product is manufactured, proc-

1 essed, packed, or held meets stand-
2 ards designed to assure that the bio-
3 logical product continues to be safe,
4 pure, and potent.
5 "(ii) DETERMINATION BY SEC-
6 RETARY.—The Secretary may determine,
7 in the Secretary's discretion, that an ele-
8 ment described in clause (i)(I) is unnecess-
9 sary in an application submitted under this
10 subsection.
11 "(iii) ADDITIONAL INFORMATION.—
12 An application submitted under this sub-
13 section—
14 "(I) shall include publicly-avail-
15 able information regarding the Sec-
16 retary's previous determination that
17 the reference product is safe, pure,
18 and potent; and
19 "(II) may include any additional
20 information in support of the applica-
21 tion, including publicly-available infor-
22 mation with respect to the reference
23 product or another biological product.
24 "(B) INTERCHANGEABILITY.—An applica-
25 tion (or a supplement to an application) sub-

1 mitted under this subsection may include infor-
2 mation demonstrating that the biological prod-
3 uct meets the standards described in paragraph
4 (4).

5 "(3) EVALUATION BY SECRETARY.—Upon re-
6 view of an application (or a supplement to an appli-
7 cation) submitted under this subsection, the Sec-
8 retary shall license the biological product under this
9 subsection if—

10 "(A) the Secretary determines that the in-
11 formation submitted in the application (or the
12 supplement) is sufficient to show that the bio-
13 logical product—

14 "(i) is biosimilar to the reference
15 product; or

16 "(ii) meets the standards described in
17 paragraph (4), and therefore is inter-
18 changeable with the reference product; and

19 "(B) the applicant (or other appropriate
20 person) consents to the inspection of the facility
21 that is the subject of the application, in accord-
22 ance with subsection (c).

23 "(4) SAFETY STANDARDS FOR DETERMINING
24 INTERCHANGEABILITY.—Upon review of an applica-
25 tion submitted under this subsection or any supple-

1 ment to such application, the Secretary shall deter-
2 mine the biological product to be interchangeable
3 with the reference product if the Secretary deter-
4 mines that the information submitted in the applica-
5 tion (or a supplement to such application) is suffi-
6 cient to show that—
7 "(A) the biological product—
8 "(i) is biosimilar to the reference
9 product; and
10 "(ii) can be expected to produce the
11 same clinical result as the reference prod-
12 uct in any given patient; and
13 "(B) for a biological product that is ad-
14 ministered more than once to an individual, the
15 risk in terms of safety or diminished efficacy of
16 alternating or switching between use of the bio-
17 logical product and the reference product is not
18 greater than the risk of using the reference
19 product without such alternation or switch.
20 "(5) GENERAL RULES.—
21 "(A) ONE REFERENCE PRODUCT PER AP-
22 PLICATION.—A biological product, in an appli-
23 cation submitted under this subsection, may not
24 be evaluated against more than 1 reference
25 product.

1 "(B) REVIEW.—An application submitted
2 under this subsection shall be reviewed by the
3 division within the Food and Drug Administra-
4 tion that is responsible for the review and ap-
5 proval of the application under which the ref-
6 erence product is licensed.
7 "(C) RISK EVALUATION AND MITIGATION
8 STRATEGIES.—The authority of the Secretary
9 with respect to risk evaluation and mitigation
10 strategies under the Federal Food, Drug, and
11 Cosmetic Act shall apply to biological products
12 licensed under this subsection in the same man-
13 ner as such authority applies to biological prod-
14 ucts licensed under subsection (a).
15 "(D) RESTRICTIONS ON BIOLOGICAL PROD-
16 UCTS CONTAINING DANGEROUS INGREDI-
17 ENTS.—If information in an application sub-
18 mitted under this subsection, in a supplement
19 to such an application, or otherwise available to
20 the Secretary shows that a biological product—
21 "(i) is, bears, or contains a select
22 agent or toxin listed in section 73.3 or
23 73.4 of title 42, section 121.3 or 121.4 of
24 title 9, or section 331.3 of title 7, Code of

1 Federal Regulations (or any successor reg-
2 ulations); or
3 "(ii) is, bears, or contains a controlled
4 substance in schedule I or II of section
5 202 of the Controlled Substances Act, as
6 listed in part 1308 of title 21, Code of
7 Federal Regulations (or any successor reg-
8 ulations);
9 the Secretary shall not license the biological
10 product under this subsection unless the Sec-
11 retary determines, after consultation with ap-
12 propriate national security and drug enforce-
13 ment agencies, that there would be no increased
14 risk to the security or health of the public from
15 licensing such biological product under this sub-
16 section.
17 "(6) EXCLUSIVITY FOR FIRST INTERCHANGE-
18 ABLE BIOLOGICAL PRODUCT.—Upon review of an
19 application submitted under this subsection relying
20 on the same reference product for which a prior bio-
21 logical product has received a determination of inter-
22 changeability for any condition of use, the Secretary
23 shall not make a determination under paragraph (4)
24 that the second or subsequent biological product is

1 interchangeable for any condition of use until the
2 earlier of—
3 "(A) 1 year after the first commercial
4 marketing of the first interchangeable bio-
5 similar biological product to be approved as
6 interchangeable for that reference product;
7 "(B) 18 months after—
8 "(i) a final court decision on all pat-
9 ents in suit in an action instituted under
10 subsection (l)(5) against the applicant that
11 submitted the application for the first ap-
12 proved interchangeable biosimilar biological
13 product; or
14 "(ii) the dismissal with or without
15 prejudice of an action instituted under sub-
16 section (l)(5) against the applicant that
17 submitted the application for the first ap-
18 proved interchangeable biosimilar biological
19 product; or
20 "(C)(i) 42 months after approval of the
21 first interchangeable biosimilar biological prod-
22 uct if the applicant that submitted such appli-
23 cation has been sued under subsection (l)(5)
24 and such litigation is still ongoing within such
25 42-month period; or

1 "(ii) 18 months after approval of the first
2 interchangeable biosimilar biological product if
3 the applicant that submitted such application
4 has not been sued under subsection (l)(5).
5 For purposes of this paragraph, the term 'final court
6 decision' means a final decision of a court from
7 which no appeal (other than a petition to the United
8 States Supreme Court for a writ of certiorari) has
9 been or can be taken.
10 "(7) EXCLUSIVITY FOR REFERENCE PROD-
11 UCT.—
12 "(A) EFFECTIVE DATE OF BIOSIMILAR AP-
13 PLICATION APPROVAL.—Approval of an applica-
14 tion under this subsection may not be made ef-
15 fective by the Secretary until the date that is
16 12 years after the date on which the reference
17 product was first licensed under subsection (a).
18 "(B) FILING PERIOD.—An application
19 under this subsection may not be submitted to
20 the Secretary until the date that is 4 years
21 after the date on which the reference product
22 was first licensed under subsection (a).
23 "(C) FIRST LICENSURE.—Subparagraphs
24 (A) and (B) shall not apply to a license for or
25 approval of—

1 "(i) a supplement for the biological
2 product that is the reference product; or
3 "(ii) a subsequent application filed by
4 the same sponsor or manufacturer of the
5 biological product that is the reference
6 product (or a licensor, predecessor in inter-
7 est, or other related entity) for—
8 "(I) a change (not including a
9 modification to the structure of the bi-
10 ological product) that results in a new
11 indication, route of administration,
12 dosing schedule, dosage form, delivery
13 system, delivery device, or strength; or
14 "(II) a modification to the struc-
15 ture of the biological product that
16 does not result in a change in safety,
17 purity, or potency.
18 "(8) PEDIATRIC STUDIES.—
19 "(A) EXCLUSIVITY.—If, before or after li-
20 censure of the reference product under sub-
21 section (a) of this section, the Secretary deter-
22 mines that information relating to the use of
23 such product in the pediatric population may
24 produce health benefits in that population, the
25 Secretary makes a written request for pediatric

1 studies (which shall include a timeframe for
2 completing such studies), the applicant or hold-
3 er of the approved application agrees to the re-
4 quest, such studies are completed using appro-
5 priate formulations for each age group for
6 which the study is requested within any such
7 timeframe, and the reports thereof are sub-
8 mitted and accepted in accordance with section
9 505A(d)(3) of the Federal Food, Drug, and
10 Cosmetic Act the period referred to in para-
11 graph (7)(A) of this subsection is deemed to be
12 12 years and 6 months rather than 12 years.
13 "(B) EXCEPTION.—The Secretary shall
14 not extend the period referred to in subpara-
15 graph (A) of this paragraph if the determina-
16 tion under section 505A(d)(3) of the Federal
17 Food, Drug, and Cosmetic Act is made later
18 than 9 months prior to the expiration of such
19 period.
20 "(C) APPLICATION OF CERTAIN PROVI-
21 SIONS.—The provisions of subsections (a), (d),
22 (e), (f), (h), (j), (k), and (l) of section 505A of
23 the Federal Food, Drug, and Cosmetic Act
24 shall apply with respect to the extension of a
25 period under subparagraph (A) of this para-

1 graph to the same extent and in the same man-
2 ner as such provisions apply with respect to the
3 extension of a period under subsection (b) or
4 (c) of section 505A of the Federal Food, Drug,
5 and Cosmetic Act.
6 "(9) GUIDANCE DOCUMENTS.—
7 "(A) IN GENERAL.—The Secretary may,
8 after opportunity for public comment, issue
9 guidance in accordance, except as provided in
10 subparagraph (B)(i), with section 701(h) of the
11 Federal Food, Drug, and Cosmetic Act with re-
12 spect to the licensure of a biological product
13 under this subsection. Any such guidance may
14 be general or specific.
15 "(B) PUBLIC COMMENT.—
16 "(i) IN GENERAL.—The Secretary
17 shall provide the public an opportunity to
18 comment on any proposed guidance issued
19 under subparagraph (A) before issuing
20 final guidance.
21 "(ii) INPUT REGARDING MOST VALU-
22 ABLE GUIDANCE.—The Secretary shall es-
23 tablish a process through which the public
24 may provide the Secretary with input re-
25 garding priorities for issuing guidance.

1 "(C) NO REQUIREMENT FOR APPLICATION
2 CONSIDERATION.—The issuance (or non-
3 issuance) of guidance under subparagraph (A)
4 shall not preclude the review of, or action on,
5 an application submitted under this subsection.
6 "(D) REQUIREMENT FOR PRODUCT CLASS-
7 SPECIFIC GUIDANCE.—If the Secretary issues
8 product class-specific guidance under subpara-
9 graph (A), such guidance shall include a de-
10 scription of—
11 "(i) the criteria that the Secretary will
12 use to determine whether a biological prod-
13 uct is highly similar to a reference product
14 in such product class; and
15 "(ii) the criteria, if available, that the
16 Secretary will use to determine whether a
17 biological product meets the standards de-
18 scribed in paragraph (4).
19 "(E) CERTAIN PRODUCT CLASSES.—
20 "(i) GUIDANCE.—The Secretary may
21 indicate in a guidance document that the
22 science and experience, as of the date of
23 such guidance, with respect to a product or
24 product class (not including any recom-
25 binant protein) does not allow approval of

1 an application for a license as provided
2 under this subsection for such product or
3 product class.
4 "(ii) MODIFICATION OR REVERSAL.—
5 The Secretary may issue a subsequent
6 guidance document under subparagraph
7 (A) to modify or reverse a guidance docu-
8 ment under clause (i).
9 "(iii) NO EFFECT ON ABILITY TO
10 DENY LICENSE.—Clause (i) shall not be
11 construed to require the Secretary to ap-
12 prove a product with respect to which the
13 Secretary has not indicated in a guidance
14 document that the science and experience,
15 as described in clause (i), does not allow
16 approval of such an application.
17 "(10) NAMING.—The Secretary shall ensure
18 that the labeling and packaging of each biological
19 product licensed under this subsection bears a name
20 that uniquely identifies the biological product and
21 distinguishes it from the reference product and any
22 other biological products licensed under this sub-
23 section following evaluation against such reference
24 product.

1 "(l) PATENT NOTICES; RELATIONSHIP TO FINAL AP-
2 PROVAL.—
3 "(1) DEFINITIONS.—For the purposes of this
4 subsection, the term—
5 "(A) 'biosimilar product' means the bio-
6 logical product that is the subject of the appli-
7 cation under subsection (k);
8 "(B) 'relevant patent' means a patent
9 that—
10 "(i) expires after the date specified in
11 subsection (k)(7)(A) that applies to the
12 reference product; and
13 "(ii) could reasonably be asserted
14 against the applicant due to the unauthor-
15 ized making, use, sale, or offer for sale
16 within the United States, or the importa-
17 tion into the United States of the bio-
18 similar product, or materials used in the
19 manufacture of the biosimilar product, or
20 due to a use of the biosimilar product in
21 a method of treatment that is indicated in
22 the application;
23 "(C) 'reference product sponsor' means the
24 holder of an approved application or license for
25 the reference product; and

1 "(D) 'interested third party' means a per-
2 son other than the reference product sponsor
3 that owns a relevant patent, or has the right to
4 commence or participate in an action for in-
5 fringement of a relevant patent.
6 "(2) HANDLING OF CONFIDENTIAL INFORMA-
7 TION.—Any entity receiving confidential information
8 pursuant to this subsection shall designate one or
9 more individuals to receive such information. Each
10 individual so designated shall execute an agreement
11 in accordance with regulations promulgated by the
12 Secretary. The regulations shall require each such
13 individual to take reasonable steps to maintain the
14 confidentiality of information received pursuant to
15 this subsection and use the information solely for
16 purposes authorized by this subsection. The obliga-
17 tions imposed on an individual who has received con-
18 fidential information pursuant to this subsection
19 shall continue until the individual returns or de-
20 stroys the confidential information, a court imposes
21 a protective order that governs the use or handling
22 of the confidential information, or the party pro-
23 viding the confidential information agrees to other
24 terms or conditions regarding the handling or use of
25 the confidential information.

1 "(3) PUBLIC NOTICE BY SECRETARY.—Within
2 30 days of acceptance by the Secretary of an appli-
3 cation filed under subsection (k), the Secretary shall
4 publish a notice identifying—
5 "(A) the reference product identified in the
6 application; and
7 "(B) the name and address of an agent
8 designated by the applicant to receive notices
9 pursuant to paragraph (4)(B).
10 "(4) EXCHANGES CONCERNING PATENTS.—
11 "(A) EXCHANGES WITH REFERENCE
12 PRODUCT SPONSOR.—
13 "(i) Within 30 days of the date of ac-
14 ceptance of the application by the Sec-
15 retary, the applicant shall provide the ref-
16 erence product sponsor with a copy of the
17 application and information concerning the
18 biosimilar product and its production. This
19 information shall include a detailed de-
20 scription of the biosimilar product, its
21 method of manufacture, and the materials
22 used in the manufacture of the product.
23 "(ii) Within 60 days of the date of re-
24 ceipt of the information required to be pro-
25 vided under clause (i), the reference prod-

1 uct sponsor shall provide to the applicant
2 a list of relevant patents owned by the ref-
3 erence product sponsor, or in respect of
4 which the reference product sponsor has
5 the right to commence an action of in-
6 fringement or otherwise has an interest in
7 the patent as such patent concerns the bio-
8 similar product.
9 "(iii) If the reference product sponsor
10 is issued or acquires an interest in a rel-
11 evant patent after the date on which the
12 reference product sponsor provides the list
13 required by clause (ii) to the applicant, the
14 reference product sponsor shall identify
15 that patent to the applicant within 30 days
16 of the date of issue of the patent, or the
17 date of acquisition of the interest in the
18 patent, as applicable.
19 "(B) EXCHANGES WITH INTERESTED
20 THIRD PARTIES.—
21 "(i) At any time after the date on
22 which the Secretary publishes a notice for
23 an application under paragraph (3), any
24 interested third party may provide notice
25 to the designated agent of the applicant

1 that the interested third party owns or has
2 rights under 1 or more patents that may
3 be relevant patents. The notice shall iden-
4 tify at least 1 patent and shall designate
5 an individual who has executed an agree-
6 ment in accordance with paragraph (2) to
7 receive confidential information from the
8 applicant.

9 "(ii) Within 30 days of the date of re-
10 ceiving notice pursuant to clause (i), the
11 applicant shall send to the individual des-
12 ignated by the interested third party the
13 information specified in subparagraph
14 (A)(i), unless the applicant and interested
15 third party otherwise agree.

16 "(iii) Within 90 days of the date of
17 receiving information pursuant to clause
18 (ii), the interested third party shall provide
19 to the applicant a list of relevant patents
20 which the interested third party owns, or
21 in respect of which the interested third
22 party has the right to commence or partici-
23 pate in an action for infringement.

24 "(iv) If the interested third party is
25 issued or acquires an interest in a relevant

1 patent after the date on which the inter-
2 ested third party provides the list required
3 by clause (iii), the interested third party
4 shall identify that patent within 30 days of
5 the date of issue of the patent, or the date
6 of acquisition of the interest in the patent,
7 as applicable.

8 "(C) IDENTIFICATION OF BASIS FOR IN-
9 FRINGEMENT.—For any patent identified under
10 clause (ii) or (iii) of subparagraph (A) or under
11 clause (iii) or (iv) of subparagraph (B), the ref-
12 erence product sponsor or the interested third
13 party, as applicable—

14 "(i) shall explain in writing why the
15 sponsor or the interested third party be-
16 lieves the relevant patent would be in-
17 fringed by the making, use, sale, or offer
18 for sale within the United States, or im-
19 portation into the United States, of the
20 biosimilar product or by a use of the bio-
21 similar product in treatment that is indi-
22 cated in the application;

23 "(ii) may specify whether the relevant
24 patent is available for licensing; and

1 "(iii) shall specify the number and
2 date of expiration of the relevant patent.
3 "(D) CERTIFICATION BY APPLICANT CON-
4 CERNING IDENTIFIED RELEVANT PATENTS.—
5 Not later than 45 days after the date on which
6 a patent is identified under clause (ii) or (iii) of
7 subparagraph (A) or under clause (iii) or (iv) of
8 subparagraph (B), the applicant shall send a
9 written statement regarding each identified pat-
10 ent to the party that identified the patent. Such
11 statement shall either—
12 "(i) state that the applicant will not
13 commence marketing of the biosimilar
14 product and has requested the Secretary to
15 not grant final approval of the application
16 before the date of expiration of the noticed
17 patent; or
18 "(ii) provide a detailed written expla-
19 nation setting forth the reasons why the
20 applicant believes—
21 "(I) the making, use, sale, or
22 offer for sale within the United
23 States, or the importation into the
24 United States, of the biosimilar prod-
25 uct, or the use of the biosimilar prod-

1 uct in a treatment indicated in the ap-
2 plication, would not infringe the pat-
3 ent; or
4 "(II) the patent is invalid or un-
5 enforceable.
6 "(5) ACTION FOR INFRINGEMENT INVOLVING
7 REFERENCE PRODUCT SPONSOR.—If an action for
8 infringement concerning a relevant patent identified
9 by the reference product sponsor under clause (ii) or
10 (iii) of paragraph (4)(A), or by an interested third
11 party under clause (iii) or (iv) of paragraph (4)(B),
12 is brought within 60 days of the date of receipt of
13 a statement under paragraph (4)(D)(ii), and the
14 court in which such action has been commenced de-
15 termines the patent is infringed prior to the date ap-
16 plicable under subsection (k)(7)(A) or (k)(8), the
17 Secretary shall make approval of the application ef-
18 fective on the day after the date of expiration of the
19 patent that has been found to be infringed. If more
20 than one such patent is found to be infringed by the
21 court, the approval of the application shall be made
22 effective on the day after the date that the last such
23 patent expires.".
24 (b) DEFINITIONS.—Section 351(i) of the Public
25 Health Service Act (42 U.S.C. 262(i)) is amended—

1 (1) by striking "In this section, the term 'bio-
2 logical product' means" and inserting the following:
3 "In this section:
4 "(1) The term 'biological product' means";
5 (2) in paragraph (1), as so designated, by in-
6 serting "protein (except any chemically synthesized
7 polypeptide)," after "allergenic product,"; and
8 (3) by adding at the end the following:
9 "(2) The term 'biosimilar' or 'biosimilarity', in
10 reference to a biological product that is the subject
11 of an application under subsection (k), means—
12 "(A) that the biological product is highly
13 similar to the reference product notwith-
14 standing minor differences in clinically inactive
15 components; and
16 "(B) there are no clinically meaningful dif-
17 ferences between the biological product and the
18 reference product in terms of the safety, purity,
19 and potency of the product.
20 "(3) The term 'interchangeable' or 'inter-
21 changeability', in reference to a biological product
22 that is shown to meet the standards described in
23 subsection (k)(4), means that the biological product
24 may be substituted for the reference product without

1 the intervention of the health care provider who pre-
2 scribed the reference product.
3 "(4) The term 'reference product' means the
4 single biological product licensed under subsection
5 (a) against which a biological product is evaluated in
6 an application submitted under subsection (k).".
7 (c) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-
8 TION 505.—
9 (1) REQUIREMENT TO FOLLOW SECTION 351.—
10 Except as provided in paragraph (2), an application
11 for a biological product shall be submitted under
12 section 351 of the Public Health Service Act (42
13 U.S.C. 262) (as amended by this Act).
14 (2) EXCEPTION.—An application for a biologi-
15 cal product may be submitted under section 505 of
16 the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 355) if—
18 (A) such biological product is in a product
19 class for which a biological product in such
20 product class is the subject of an application
21 approved under such section 505 not later than
22 the date of enactment of this Act; and
23 (B) such application—
24 (i) has been submitted to the Sec-
25 retary of Health and Human Services (re-

1 ferred to in this Act as the "Secretary")
2 before the date of enactment of this Act;
3 or
4 (ii) is submitted to the Secretary not
5 later than the date that is 10 years after
6 the date of enactment of this Act.
7 (3) LIMITATION.—Notwithstanding paragraph
8 (2), an application for a biological product may not
9 be submitted under section 505 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 355) if there is
11 another biological product approved under sub-
12 section (a) of section 351 of the Public Health Serv-
13 ice Act that could be a reference product with re-
14 spect to such application (within the meaning of
15 such section 351) if such application were submitted
16 under subsection (k) of such section 351.
17 (4) DEEMED APPROVED UNDER SECTION 351.—
18 An approved application for a biological product
19 under section 505 of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 355) shall be deemed to be
21 a license for the biological product under such sec-
22 tion 351 on the date that is 10 years after the date
23 of enactment of this Act.
24 (5) DEFINITIONS.—For purposes of this sub-
25 section, the term "biological product" has the mean-

1 ing given such term under section 351 of the Public
2 Health Service Act (42 U.S.C. 262) (as amended by
3 this Act).

4 **SEC. ___. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
5 **PRODUCTS.**

6 Subparagraph (B) of section 735(1) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is
8 amended by inserting ", including licensure of a biological
9 product under section 351(k) of such Act" before the pe-
10 riod at the end.