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**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:

1                   **Subtitle \_\_\_\_\_—Pathway for**  
2                                   **Biosimilars**

3   **SEC. \_\_\_\_ . LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGI-**  
4                                   **CAL PRODUCTS.**

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

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

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

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

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

17               “(2) CONTENT.—

18               “(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-

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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-

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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 unneces-  
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-

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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-

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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 applica-  
23       tion submitted under this subsection, may not  
24       be evaluated against more than 1 reference  
25       product.

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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

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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



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1 interchangeably 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

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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

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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.

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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

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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           “(1) 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



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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.

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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-

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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

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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

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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-

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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—

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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



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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-

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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-

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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.



