

111TH CONGRESS
1ST SESSION

S. 726

To amend the Public Health Service Act to provide for the licensing of biosimilar and biogeneric biological products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 26, 2009

Mr. SCHUMER (for himself, Ms. COLLINS, Mr. BROWN, Mr. VITTER, Ms. STABENOW, Mr. MARTINEZ, and Mrs. SHAHEEN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to provide for the licensing of biosimilar and biogeneric biological products, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Promoting Innovation
5 and Access to Life-Saving Medicine Act”.

6 **SEC. 2. DEFINITIONS.**

7 (a) LICENSURE.—Section 351(i) of the Public Health
8 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”; and

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

6 “(2) The term ‘abbreviated biological product
7 application’ means an abbreviated application for a
8 license of a biological product that relies in part on
9 data or information in an application for another bi-
10 ological product licensed under this section or ap-
11 proved under section 505 of the Federal Food,
12 Drug, and Cosmetic Act.

13 “(3) The term ‘reference product’ means the
14 single licensed biological product, approved under
15 subsection (a) or (k), against which a biological
16 product is evaluated for demonstration of safety, po-
17 tency, or purity.

18 “(4) The term ‘final action’ means, with respect
19 to an abbreviated biological product application, the
20 Secretary’s issuance of a final action letter to the
21 sponsor of an abbreviated biological product applica-
22 tion which—

23 “(A) approves the application; or

24 “(B) disapproves the application and sets
25 forth in detail an enumeration of the specific

1 deficiencies in the particular application and of
2 the specific, enumerated actions the sponsor
3 would be required to take in order for the spon-
4 sor to receive a final action letter that approves
5 such application.

6 “(5) The term ‘final action date’ means, with
7 respect to an abbreviated biological product applica-
8 tion, the date by which the Secretary must take a
9 final action on the application pursuant to sub-
10 section (k)(13).

11 “(6) The term ‘reviewing division’ means the
12 division responsible for the review of an application
13 for approval of a biological product (including all sci-
14 entific and medical matters, chemistry, manufac-
15 turing, and controls).”

16 (b) FEES.—

17 (1) RULE OF CONSTRUCTION.—The definition
18 of a human drug application in section 735(1) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379g(1)) shall be construed to include applications
21 under section 351(k) of the Public Health Service
22 Act, as added by section 3, in addition to applica-
23 tions under section 351(a) of such Act.

24 (2) SUPPLEMENT.—Section 735(2) of the Fed-
25 eral Food, Drug, and Cosmetic Act (21 U.S.C.

1 379g(2)) is amended by adding at the end the fol-
 2 lowing: “Notwithstanding the preceding sentence,
 3 any request for an interchangeability determination
 4 under section 351(k) of the Public Health Service
 5 Act shall be treated as a supplement for purposes of
 6 this part, irrespective of whether such request is in-
 7 cluded in an application for licensure of a biological
 8 product or a subsequent submission.”.

9 **SEC. 3. REGULATION OF BIOSIMILAR AND BIOGENERIC BI-**
 10 **OLOGICAL PRODUCTS.**

11 (a) IN GENERAL.—Section 351 of the Public Health
 12 Service Act (42 U.S.C. 262), as amended by section 2,
 13 is further amended—

14 (1) in subsection (a)(1)(A), by inserting “under
 15 this subsection or subsection (k)” after “biologics li-
 16 cense”; and

17 (2) by adding at the end the following sub-
 18 section:

19 “(k) REGULATION OF BIOSIMILAR AND INTER-
 20 CHANGEABLE BIOLOGICAL PRODUCTS.—

21 “(1) BIOSIMILAR.—In this subsection, the term
 22 ‘biosimilar’ or ‘biosimilarity’, in reference to a bio-
 23 logical product, means no clinically meaningful dif-
 24 ferences between the biological product and the ref-
 25 erence product would be expected in terms of the

1 safety, purity, and potency if treatment were to be
2 initiated with the biological product instead of the
3 reference product.

4 “(2) INTERCHANGEABILITY.—In this sub-
5 section, the term ‘interchangeable’ or ‘interchange-
6 ability’ means, with respect to a given condition of
7 use, that—

8 “(A) the biological product is biosimilar to
9 the reference product; and

10 “(B) if the biological product is intended
11 to be administered more than once to a given
12 patient, the patient can be switched one or
13 more times between the reference product and
14 the biological product without an expected in-
15 crease in the risk of adverse effects, including
16 a clinically significant change in immunogenici-
17 ty, or diminished effectiveness, compared to the
18 expected risks from continuing to use the ref-
19 erence product without such switching.

20 “(3) SUBMISSION OF AN ABBREVIATED BIO-
21 LOGICAL PRODUCT APPLICATION.—Any person may
22 file with the Secretary an abbreviated biological
23 product application. Any such application shall in-
24 clude the following:

1 “(A) Information demonstrating that the
2 biological product and reference product contain
3 highly similar molecular structural features,
4 notwithstanding minor differences in hetero-
5 geneity profile, impurities, or degradation pat-
6 terns.

7 “(B) Information demonstrating that the
8 biological product is biosimilar to (as defined in
9 paragraph (1)) or interchangeable with (as de-
10 fined in paragraph (2)) the reference product
11 for the condition or conditions of use pre-
12 scribed, recommended, or suggested in the pro-
13 posed labeling based upon, in the discretion of
14 the Secretary—

15 “(i) information derived from chem-
16 ical, physical, and biological assays, and
17 other non-clinical laboratory studies; and

18 “(ii) information from any necessary
19 clinical study or studies sufficient to con-
20 firm safety, purity, and potency.

21 Any studies under clause (ii) shall be designed
22 to avoid duplicative and unethical clinical test-
23 ing.

24 “(C) Information demonstrating that the
25 biological product and reference product utilize

1 the same mechanism or mechanisms of action
2 for the condition or conditions of use pre-
3 scribed, recommended, or suggested in the pro-
4 posed labeling, but only to the extent the mech-
5 anism or mechanisms of action are known for
6 the reference product or can reasonably be de-
7 termined. If the applicant seeks to rely on a
8 demonstration of biosimilarity or interchange-
9 ability for a single condition of use to support
10 approval of additional conditions of use that
11 share the same mechanism or mechanisms of
12 action, information demonstrating that such re-
13 liance is scientifically appropriate.

14 “(D) Information to show that the condi-
15 tion or conditions of use prescribed, rec-
16 ommended, or suggested in the proposed label-
17 ing for the biological product have been pre-
18 viously approved for the reference product.

19 “(E) Information to show that the route of
20 administration, the dosage form, and the
21 strength of the biological product are the same
22 as those of the reference product.

23 “(F) Information demonstrating that the
24 facility in which the biological product is manu-
25 factured, processed, packed, or held meets

1 standards designed to ensure that the biological
2 product continues to be safe, pure, and potent.

3 “(4) OTHER APPLICATIONS.—Any person, in-
4 cluding a person who has not conducted and does
5 not have a right of reference to the studies in the
6 application for a reference product, may submit an
7 abbreviated biological product application under this
8 paragraph for a biological product that differs from,
9 or incorporates a change to, the reference product
10 with respect to one or more characteristics described
11 in subparagraphs (A) through (E) of paragraph (3),
12 including a difference in safety, purity, or potency,
13 so long as the application contains sufficient infor-
14 mation to establish the safety, purity, and potency of
15 the biological product for its proposed condition or
16 conditions of use.

17 “(5) APPROVAL OF BIOSIMILAR OR INTER-
18 CHANGEABLE BIOLOGICAL PRODUCTS.—

19 “(A) DETERMINATION OF BIOSIMI-
20 LARITY.—Upon review of an application sub-
21 mitted under paragraph (3) for a biological
22 product and any other information available to
23 the Secretary, including information in the ap-
24 plication for the reference product, the Sec-
25 retary shall issue a biosimilar biological product

1 license for the conditions of use prescribed, rec-
2 ommended, or suggested in the proposed label-
3 ing for the product, unless the Secretary finds
4 and informs the applicant (including provision
5 of a detailed explanation) that—

6 “(i) information submitted in the ap-
7 plication and any other information avail-
8 able to the Secretary is insufficient to show
9 that the biological product and the ref-
10 erence product contain highly similar mo-
11 lecular structural features, notwithstanding
12 minor differences in heterogeneity profile,
13 impurities, or degradation patterns;

14 “(ii) information submitted in the ap-
15 plication and any other information avail-
16 able to the Secretary is insufficient to show
17 that the biological product is biosimilar to
18 the reference product for the condition or
19 conditions of use prescribed, recommended,
20 or suggested in the labeling proposed in
21 the application;

22 “(iii) information submitted in the ap-
23 plication and any other information avail-
24 able to the Secretary is insufficient to show
25 that the biological product and reference

1 product utilize the same mechanism or
2 mechanisms of action for the conditions of
3 use prescribed, recommended, or suggested
4 in the proposed labeling for the biological
5 product, unless the mechanism or mecha-
6 nisms of action are not known and cannot
7 reasonably be determined for the reference
8 product for such condition or conditions;

9 “(iv) if the applicant has dem-
10 onstrated biosimilarity for a single condi-
11 tion of use sharing the same mechanism of
12 action as other conditions of use of the ref-
13 erence product, and has sought approval of
14 one or more such other conditions of use
15 on the basis of such demonstration, infor-
16 mation submitted in the application and
17 any other information available to the Sec-
18 retary is insufficient to show the safety,
19 purity, and potency of one or more such
20 other conditions of use;

21 “(v) information submitted in the ap-
22 plication and any other information avail-
23 able to the Secretary is insufficient to show
24 that the route of administration, the dos-
25 age form, and the strength of the biological

1 product are the same as those of the ref-
2 erence product;

3 “(vi) information submitted in the ap-
4 plication and any other information avail-
5 able to the Secretary is insufficient to show
6 that the condition or conditions of use pre-
7 scribed, recommended, or suggested in the
8 proposed labeling for the biological product
9 are limited to one or more of the same use
10 or uses as have been previously approved
11 for the reference product;

12 “(vii) information submitted in the
13 application and any other information
14 available to the Secretary shows (I) the in-
15 active ingredients of the biological product
16 are unsafe for use under the conditions
17 prescribed, recommended, or suggested in
18 the proposed labeling for the biological
19 product, or (II) the composition of the bio-
20 logical product is unsafe under such condi-
21 tions because of the type or quantity of in-
22 active ingredients included or the manner
23 in which the inactive ingredients are in-
24 cluded;

1 “(viii) information submitted in the
2 application and any other information
3 available to the Secretary fails to dem-
4 onstrate that the facility in which the bio-
5 logical product is manufactured, processed,
6 packed, or held meets standards designed
7 to ensure that the biological product con-
8 tinues to be safe, pure, and potent;

9 “(ix) the Secretary has, for reasons of
10 safety, purity, or potency, other than rea-
11 sons that are unique to the reference prod-
12 uct—

13 “(I) withdrawn or suspended the
14 license of the reference product;

15 “(II) published a notice of oppor-
16 tunity for hearing to withdraw such li-
17 cense; or

18 “(III) determined that the ref-
19 erence product has been withdrawn
20 from sale; or

21 “(x) the application contains an un-
22 true statement of material fact.

23 “(B) DETERMINATIONS ON INTERCHANGE-
24 ABILITY.—Subject to subparagraph (C) and
25 paragraph (11), upon issuing a product license

1 for a biological product under subparagraph
2 (A), the Secretary shall make and publish one
3 of the following determinations:

4 “(i) Such product is interchangeable
5 with the reference product for one or more
6 specified conditions of use prescribed, rec-
7 ommended, or suggested in the labeling of
8 the biological product.

9 “(ii) Interchangeability has not been
10 established, but the approved product is as
11 safe and effective for its approved uses as
12 the reference product.

13 “(C) DETERMINATION OF INTERCHANGE-
14 ABILITY OF SUBSEQUENT BIOLOGICAL PROD-
15 UCT.—If the Secretary determines that an ap-
16 plication meets the approval requirements of
17 subparagraph (A), and, prior to the issuance of
18 a product license, the Secretary has made a de-
19 termination of interchangeability of another bio-
20 logical product and the reference product for
21 which the exclusivity period under paragraph
22 (11) has not expired, the Secretary shall—

23 “(i) issue the product license for the
24 subsequent biological product; and

1 “(ii) defer issuing any determination
2 of interchangeability as to the subsequent
3 biological product and the reference prod-
4 uct until the exclusivity period under para-
5 graph (11) has expired.

6 “(6) DESIGNATION OF OFFICIAL NAME.—

7 “(A) IN GENERAL.—If, pursuant to section
8 508 of the Federal Food, Drug, and Cosmetic
9 Act, the Secretary determines that designation
10 of an official name for a biosimilar biological
11 product is necessary or desirable in the inter-
12 ests of usefulness or simplicity, the Secretary
13 shall designate the same official name for the
14 biosimilar biological product as the Secretary
15 designated for the reference product.

16 “(B) LIMITATION.—This paragraph shall
17 not apply to products approved under para-
18 graph (7).

19 “(C) REPORT TO CONGRESS.—Not later
20 than 5 years after the date of the enactment of
21 this subsection, the Comptroller General of the
22 United States shall submit a report to the Con-
23 gress on public health and economic impacts as-
24 sociated with practices for designating the offi-
25 cial names of biosimilar biological products in

1 the United States and in other countries that
2 approve biosimilar biological products.

3 “(7) OTHER APPROVAL PROVISIONS.—The Sec-
4 retary shall approve an application for a license sub-
5 mitted under paragraph (4) if the application and
6 any other information available to the Secretary, in-
7 cluding information in the application for the ref-
8 erence product, are sufficient to establish the safety,
9 purity, and potency of the biosimilar biological prod-
10 uct for the proposed condition or conditions of use
11 for such product.

12 “(8) ESTABLISHING INTERCHANGEABILITY FOR
13 BIOSIMILAR BIOLOGICAL PRODUCTS.—

14 “(A) IN GENERAL.—In an original applica-
15 tion or a supplement to an application under
16 this subsection, an applicant may submit infor-
17 mation to the Secretary to demonstrate the
18 interchangeability of a biosimilar biological
19 product and the reference product. An applicant
20 may withdraw a request for an interchange-
21 ability determination at any time. A request for
22 an interchangeability determination submitted
23 after the filing of an application shall be consid-
24 ered a major amendment to the application. Ex-
25 cept as provided in paragraph (11), nothing in

1 this subsection shall be construed to prohibit
2 the Secretary from making a determination of
3 interchangeability at any time after approval.

4 “(B) GUIDANCE.—Within 2 years after en-
5 actment of this subsection, the Secretary shall
6 issue guidance regarding standards and require-
7 ments for interchangeability. The Secretary is
8 authorized to make determinations of inter-
9 changeability under paragraph (5)(B) prior to
10 issuing guidance under this subparagraph.

11 “(9) INTERCHANGEABILITY LABELING FOR
12 INTERCHANGEABLE BIOLOGICAL PRODUCTS.—Ex-
13 cept as provided in paragraph (11), upon a deter-
14 mination of interchangeability, the Secretary shall,
15 at the request of the applicant, provide for the label
16 of the interchangeable biological product to include
17 a statement that the biological product is inter-
18 changeable with the reference product for the condi-
19 tions of use prescribed, recommended, or suggested
20 in the labeling for which interchangeability has been
21 established.

22 “(10) DELAY OF APPROVAL.—

23 “(A) APPLICABLE DELAY PERIOD.—

24 “(i) 5-YEAR PERIOD.—If an applica-
25 tion under this subsection refers to a bio-

1 logical product described in clause (i) of
2 subparagraph (B), the Secretary may not
3 approve such application before the expira-
4 tion of—

5 “(I) the 5-year period beginning
6 on such product’s approval date; or

7 “(II) such period, as extended
8 under subparagraph (D).

9 “(ii) 3-YEAR PERIOD.—If an applica-
10 tion under this subsection refers to a bio-
11 logical product described in subparagraph
12 (C), the Secretary may not approve such
13 application for the conditions of approval
14 of such product before the expiration of—

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

17 “(II) such period, as extended
18 under subparagraph (D).

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

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

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

1 “(II) no major substance of the
2 product, nor any highly similar major
3 substance, has been approved in any
4 other application under subsection (a);

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

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

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

21 “(I) Protein biological products
22 that differ in structure solely due to
23 post-translational events, infidelity of
24 translation or transcription, or minor
25 differences in amino acid sequence.

1 “(II) Polysaccharide biological
2 products with similar saccharide re-
3 peating units, even if the number of
4 units differ and even if there are dif-
5 ferences in post-polymerization modi-
6 fications.

7 “(III) Glycosylated protein prod-
8 ucts that differ in structure solely due
9 to post-translational events, infidelity
10 of translation or transcription, or
11 minor differences in amino acid se-
12 quence, and if they had similar sac-
13 charide repeating units, even if the
14 number of units differ and even if
15 there were differences in post-polym-
16 erization modifications.

17 “(IV) Polynucleotide biological
18 products with identical sequence of
19 purine and pyrimidine bases (or their
20 derivatives) bound to an identical
21 sugar backbone (ribose, deoxyribose,
22 or modifications of these sugars).

23 “(V) Closely related, complex
24 partly definable biological products
25 with similar therapeutic intent, such

1 as live viral products for the same in-
2 dication.

3 The Secretary may by regulation identify
4 additional biological products not described
5 in clause (i).

6 “(C) MAJOR SUBSTANCE PREVIOUSLY AP-
7 PROVED.—A biological product is described in
8 this subparagraph if—

9 “(i) an application is submitted for
10 such product under subsection (a);

11 “(ii) such product includes a major
12 substance that has been approved in an-
13 other application under subsection (a), or
14 any highly similar major substance;

15 “(iii) the application submitted for
16 such product is approved after the date of
17 the enactment of this subsection;

18 “(iv) the application submitted for
19 such product contains reports of new clin-
20 ical investigations (other than pharmaco-
21 kinetic or pharmacodynamic studies) es-
22 sential to the approval of the application
23 and conducted or sponsored by the appli-
24 cant; and

1 “(v) the product represents a signifi-
2 cant therapeutic advance, which may in-
3 clude demonstration of safety, purity, and
4 potency for a significant new indication or
5 subpopulation, other than a pediatric sub-
6 population.

7 “(D)(i) SUPPLEMENT.—If a supplement to
8 an application approved under subsection (a) is
9 approved no later than 1 year before the expira-
10 tion of a period to which the applicant is enti-
11 tled under subparagraph (A), the period de-
12 scribed in subparagraph (A) shall, except as
13 provided in clause (ii), be extended by 6 months
14 if—

15 “(I) the supplement contains reports
16 of new clinical investigations (other than
17 pharmacokinetic or pharmacodynamic
18 studies) essential to the approval of the
19 supplement and conducted or sponsored by
20 the person submitting the supplement; and

21 “(II) the change provides a significant
22 therapeutic advance, which may include
23 demonstration of safety, purity, and po-
24 tency for a significant new indication or

1 subpopulation, other than a pediatric sub-
2 population.

3 “(ii) ADJUSTMENT.—Any period of market
4 exclusivity extended under subclause (I) or (II)
5 of clause (i) for a biological product shall be re-
6 duced by 3 months if the organization des-
7 ignated under subparagraph (E) notifies the
8 Secretary that, with respect to any major sub-
9 stance contained in the biological product, the
10 combined annual gross sales in the United
11 States for all biological products—

12 “(I) containing the major substance;
13 and

14 “(II) owned or marketed by the appli-
15 cant or its affiliates;

16 exceeded \$1,000,000,000 in the calendar year
17 preceding approval of the supplement involved.

18 “(iii) LIMITATION.—Only one extension
19 under this subparagraph may be granted for
20 any biological product.

21 “(E)(i) DESIGNATION.—The Secretary
22 shall designate an organization other than the
23 Food and Drug Administration to make the de-
24 termination of combined annual gross sales de-
25 scribed in clause (ii). Prior to designating such

1 organization, the Secretary shall determine that
2 such organization is independent and is quali-
3 fied to evaluate the sales of pharmaceutical
4 products. The Secretary shall re-evaluate the
5 designation of such organization once every 3
6 years.

7 “(ii) NOTIFICATION.—The organization
8 designated under clause (i) shall—

9 “(I) determine, with respect to each
10 major substance contained in each biologi-
11 cal product that is the subject of a pending
12 supplement under subparagraph (D)(i), the
13 amount of the combined annual gross sales
14 in the United States in the preceding cal-
15 endar year for all biological products—

16 “(aa) containing the major sub-
17 stance; and

18 “(bb) owned or marketed by the
19 applicant or its affiliates; and

20 “(II) notify the Secretary of such de-
21 termination.

22 “(F) DEFINITION.—In this paragraph, the
23 term ‘approval date’ means the date of approval
24 of an application for the biological product
25 under subsection (a).

1 “(11) EXCLUSIVITY.—

2 “(A) IN GENERAL.—Upon review of an ab-
3 breviated biological product application relying
4 on the same reference product for which a prior
5 biological product has received a determination
6 of interchangeability for any condition of use,
7 the Secretary shall not make a determination
8 under paragraph (5)(B) that the second or sub-
9 sequent biological product is interchangeable for
10 any condition of use, and no holder of a biologi-
11 cal product license approved under subsection
12 (a) shall manufacture, market, sell, or dis-
13 tribute a rebranded interchangeable biological
14 product, directly or indirectly, or authorize any
15 other person to manufacture, market, sell, or
16 distribute a rebranded interchangeable biologi-
17 cal product, for any condition of use, until the
18 earlier of—

19 “(i) 180 days after the first commer-
20 cial marketing of the first interchangeable
21 biological product to be approved as inter-
22 changeable for that reference product;

23 “(ii) one year after—

24 “(I) a final court decision in
25 favor of the applicant on all patents in

1 suit in an action instituted under
2 paragraph (18)(C) against the appli-
3 cant that submitted the application
4 for the first approved interchangeable
5 biological product; or

6 “(II) the dismissal with or with-
7 out prejudice of an action instituted
8 under paragraph (18)(C) against the
9 applicant that submitted the applica-
10 tion for the first approved inter-
11 changeable biological product; or

12 “(iii)(I) 36 months after approval of
13 the first interchangeable biological product
14 if the applicant has been sued under para-
15 graph (18)(C) and such litigation is still
16 ongoing within such 36-month period; or

17 “(II) one year after approval in the
18 event that the first approved interchange-
19 able biological product applicant has not
20 been sued under paragraph (18)(C).

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

1 “(B) REBRANDED INTERCHANGEABLE BI-
2 OLOGICAL PRODUCT.—For purposes of this sub-
3 section, the term ‘rebranded interchangeable bi-
4 ological product’—

5 “(i) means any rebranded inter-
6 changeable version of the reference product
7 involved that the holder of the biological
8 product license approved under subsection
9 (a) for that reference product seeks to
10 commence marketing, selling, or distrib-
11 uting, directly or indirectly; and

12 “(ii) does not include any product to
13 be marketed, sold, or distributed—

14 “(I) by an entity eligible for ex-
15 clusivity with respect to such product
16 under this paragraph; or

17 “(II) after expiration of any ex-
18 clusivity with respect to such product
19 under this paragraph.

20 “(12) HEARING.—If the Secretary decides to
21 disapprove an abbreviated biological product applica-
22 tion, the Secretary shall give the applicant notice of
23 an opportunity for a hearing before the Secretary on
24 the question of whether such application is approv-
25 able. If the applicant elects to accept the opportunity

1 for hearing by written request within 30 days after
2 such notice, such hearing shall commence not more
3 than 90 days after the expiration of such 30 days
4 unless the Secretary and the applicant otherwise
5 agree. Any such hearing shall thereafter be con-
6 ducted on an expedited basis, and the Secretary's
7 order thereon shall be issued within 90 days after
8 the date fixed by the Secretary for filing final briefs.

9 “(13) FINAL ACTION DATE.—

10 “(A) IN GENERAL.—The Secretary shall
11 take a final action on an abbreviated biological
12 product application by the date that is 10 cal-
13 endar months following the sponsor's submis-
14 sion of such application, or 180 days following
15 the Secretary's notification to the applicant that
16 its application has been accepted for filing,
17 whichever is earlier.

18 “(B) EXTENSION.—The final action date
19 provided by subparagraph (A) with respect to
20 an application may be extended for such period
21 of time as is agreed to by the Secretary and the
22 applicant in a jointly executed written agree-
23 ment that is counter-signed by the Secretary
24 and the applicant no later than 30 days prior
25 to—

1 “(i) such final action date; or

2 “(ii) the date on which any prior ex-
3 tension under this subparagraph expires.

4 “(14) REQUEST FOR DELAY OF FINAL AC-
5 TION.—Subject to paragraph (19)(A)(i) and not-
6 withstanding any other provision of law, the Sec-
7 retary shall not fail or refuse to take a final action
8 on an abbreviated biological product application by
9 the final action date on the basis that a person,
10 other than the biosimilar biological product appli-
11 cant, has requested (in a petition or otherwise) that
12 the Secretary refuse to take or otherwise defer such
13 final action, and no court shall enjoin the Secretary
14 from taking final action or stay the effect of final
15 action previously taken by the Secretary, except by
16 issuance of a permanent injunction based upon an
17 express finding of clear and convincing evidence that
18 the person seeking to have the Secretary refuse to
19 take or otherwise to defer final action by the final
20 action date—

21 “(A) has prevailed on the merits of the
22 person’s complaint against the Secretary;

23 “(B) will suffer imminent and actual irrepar-
24 able injury, constituting more than irrecover-
25 able economic loss, and that also will threaten

1 imminent destruction of such person’s business;
2 and

3 “(C) has an interest that outweighs the
4 overwhelming interest that the public has in ob-
5 taining prompt access to a biosimilar biological
6 product.

7 “(15) REPORT ON EXTENSIONS OF FINAL AC-
8 TION DATE.—The Secretary shall prepare and sub-
9 mit to the President, the Committee on Energy and
10 Commerce of the House of Representatives, and the
11 Committee on Health, Education, Labor, and Pen-
12 sions of the Senate a report regarding any jointly
13 executed written agreement to extend the final ac-
14 tion date under this Act within 15 calendar days
15 after the joint execution of any such written agree-
16 ment.

17 “(16) REPORT ON FAILURE TO TAKE FINAL AC-
18 TION.—The Secretary shall prepare and submit an-
19 nually to the President, the Committee on Energy
20 and Commerce of the House of Representatives, and
21 the Committee on Health, Education, Labor, and
22 Pensions of the Senate a report detailing the specific
23 and particularized reasons enumerated by the re-
24 viewing division for each instance of the Secretary’s

1 failure to take final action by the final action date
2 in the previous year.

3 “(17) REGULATIONS.—The Secretary shall es-
4 tablish, by regulation within 2 years after the date
5 of the enactment of this subsection, requirements for
6 the efficient review, approval, suspension, and rev-
7 ocation of abbreviated biological product applications
8 under this subsection. The Secretary may not use
9 the absence of final regulations as a basis for the
10 Secretary to fail to act on an application submitted
11 under this subsection.

12 “(18) PATENTS.—

13 “(A) REQUEST FOR PATENT INFORMA-
14 TION.—

15 “(i) IN GENERAL.—At any time, in-
16 cluding at the initial stages of develop-
17 ment, an applicant or a prospective appli-
18 cant under this subsection may send a
19 written request for patent information to
20 the holder of the approved application for
21 the reference product. The holder of the
22 approved application for the reference
23 product shall, not later than 60 days after
24 the date on which the holder receives the
25 request, provide to the applicant or pro-

1 spective applicant a list of all those patents
2 owned by, licensed to, or otherwise under
3 the control of, the holder of the approved
4 application that the holder believes in good
5 faith relate to the reference product, in-
6 cluding patents that claim the approved bi-
7 ological product, any formulation of such
8 product, any method of using such prod-
9 uct, any component of such product, or
10 any method or process that can be used to
11 manufacture such product or component,
12 regardless of whether that method or proc-
13 ess is used to manufacture the reference
14 product.

15 “(ii) UPDATES.—For a period of 2
16 years beginning on the date on which the
17 holder of the approved application for the
18 reference product receives the request for
19 information, the holder shall send to the
20 applicant or prospective applicant updates
21 of its response to the request for informa-
22 tion by identifying all relevant patents
23 issued or licensed to the holder after the
24 initial response under clause (i). Any such
25 update must be provided, in the case of a

1 new patent, not later than 30 days after
2 the date on which the patent is issued and,
3 in the case of a license, not later than 30
4 days after the date on which the holder ob-
5 tains the license.

6 “(iii) ADDITIONAL REQUESTS.—The
7 applicant may submit additional requests
8 under clause (i) for patent information,
9 and each such request shall be subject to
10 the requirements of this paragraph.

11 “(iv) NOTIFICATION TO PATENT
12 HOLDER.—Within 30 days of receiving a
13 request under this subparagraph, the hold-
14 er of the approved application for the ref-
15 erence product shall give notice of such re-
16 quest to the owner of any patent licensed
17 to, or otherwise under the control of, the
18 holder that is identified by the holder pur-
19 suant to clause (i).

20 “(B) PATENT NOTIFICATIONS.—At any
21 time after submitting an application under this
22 subsection, the applicant may provide a notice
23 of the application with respect to any one or
24 more patents identified by the holder of the ref-
25 erence product pursuant to subparagraph (A)

1 or with respect to any one or more patents
2 owned by, licensed to, or otherwise under the
3 control of the holder of the approved applica-
4 tion, but not identified pursuant to subpara-
5 graph (A). An applicant may submit additional
6 notices at any time, and each notice shall be
7 subject to the provisions of this subparagraph.
8 Each notice shall—

9 “(i) be sent to the holder of the ap-
10 proved application for the reference prod-
11 uct and to the owner of any patent identi-
12 fied by the holder pursuant to subpara-
13 graph (A);

14 “(ii) include a detailed statement of
15 the factual and legal bases for the appli-
16 cant’s belief that the patents included in
17 the notice are invalid, are unenforceable, or
18 will not be infringed by the commercial
19 sale of the product for which approval is
20 being sought under this subsection; and

21 “(iii) be submitted to the Federal
22 Trade Commission, which shall treat such
23 notice as confidential.

24 “(C) ACTION FOR INFRINGEMENT.—With-
25 in 45 days after the date on which the holder

1 of the approved application for the reference
2 product, or the owner of a patent, receives a no-
3 tice under subparagraph (B), the holder or pat-
4 ent owner may bring an action for infringement
5 only with respect to the patent or patents in-
6 cluded in the notice.

7 “(D) LIMITATION ON DECLARATORY JUDG-
8 MENT ACTIONS.—With respect to any patent re-
9 lating to a product that is the subject of an ap-
10 plication under this subsection, the recipient of
11 a notice under subparagraph (B) with respect
12 to that application may not, prior to the com-
13 mercial marketing of the product, bring any ac-
14 tion under section 2201 of title 28, United
15 States Code, for a declaration of infringement,
16 validity, or enforceability of any such patent
17 that was not identified in the notice.

18 “(E) DECLARATORY JUDGMENT ACTION.—

19 “(i) IN GENERAL.—With respect to
20 any patent identified in a notification
21 under subparagraph (A) or (B) for which
22 the holder, or the owner of the patent—

23 “(I) has not brought an action
24 for infringement under subparagraph
25 (C); or

1 “(II) has brought an action for
2 infringement under subparagraph (C),
3 but subsequently dismissed that ac-
4 tion without prejudice;

5 the applicant may bring an action for a de-
6 claratory judgment under section 2201 of
7 title 28, United States Code, that such
8 patent is invalid or not infringed by the bi-
9 ological product at issue.

10 “(ii) CASE OR CONTROVERSY.—The
11 courts of the United States shall have, and
12 shall exercise, subject matter jurisdiction
13 to hear such an action to the full extent
14 permitted by article III of the Constitu-
15 tion.

16 “(F) DISCRETION OF APPLICANTS.—An
17 applicant or prospective applicant for a bio-
18 similar biological product under this subsection
19 may not be compelled, by court order or other-
20 wise, to initiate the procedures set forth in this
21 paragraph. Nothing in this paragraph requires
22 an applicant or a prospective applicant to in-
23 voke the procedures set forth in this paragraph.

24 “(19) PETITIONS AND CIVIL ACTIONS REGARD-
25 ING APPROVAL OF CERTAIN APPLICATIONS.—

1 “(A) IN GENERAL.—With respect to a
2 pending application submitted under paragraph
3 (3) or (4), if a petition is submitted to the Sec-
4 retary that seeks to have the Secretary take, or
5 refrain from taking, any form of action relating
6 to the approval of the application, including a
7 delay in the effective date of the application,
8 the following applies, subject to subparagraph
9 (E):

10 “(i)(I) The Secretary may not, on the
11 basis of the petition, delay approval of the
12 application unless the Secretary deter-
13 mines, within 30 days after receiving the
14 petition, that a delay is necessary to pro-
15 tect the public health. Consideration of a
16 petition shall be separate and apart from
17 the review and approval of the application.

18 “(II) With respect to a determination
19 by the Secretary under subclause (I) that
20 a delay is necessary to protect the public
21 health:

22 “(aa) The Secretary shall publish
23 on the Internet site of the Food and
24 Drug Administration a statement pro-

1 viding the reasons underlying the de-
2 termination.

3 “(bb) Not later than 10 days
4 after making the determination, the
5 Secretary shall provide notice to the
6 sponsor of the application and an op-
7 portunity for a meeting with the Com-
8 missioner to discuss the determina-
9 tion.

10 “(ii) The Secretary shall take final
11 agency action on the petition not later
12 than 180 days after the date on which the
13 petition is submitted. The Secretary shall
14 not extend such period, even with the con-
15 sent of the petitioner, for any reason, in-
16 cluding based upon the submission of com-
17 ments relating to the petition or supple-
18 mental information supplied by the peti-
19 tioner.

20 “(iii) The Secretary may not consider
21 the petition for review unless it is signed
22 and contains the following verification: ‘I
23 certify that, to my best knowledge and be-
24 lief: (a) this petition includes all informa-
25 tion and views upon which the petition re-

1 lies; (b) this petition includes representa-
2 tive data and/or information known to the
3 petitioner which are unfavorable to the pe-
4 tition; and (c) I have taken reasonable
5 steps to ensure that any representative
6 data and/or information which are unfavor-
7 able to the petition were disclosed to me.
8 I further certify that the information upon
9 which I have based the action requested
10 herein first became known to the party on
11 whose behalf this petition is submitted on
12 or about the following date: [_____]. I re-
13 ceived or expect to receive payments, in-
14 cluding cash and other forms of consider-
15 ation, from the following persons or orga-
16 nizations to file this petition: [_____]. I
17 verify under penalty of perjury that the
18 foregoing is true and correct.’.

19 “(B) DENIAL BASED ON INTENT TO
20 DELAY.—If the Secretary determines that a pe-
21 tition or supplement to the petition was sub-
22 mitted with the primary purpose of delaying the
23 licensure or the approval of a condition of use
24 for a biological product, the Secretary may deny
25 the petition at any point based on such deter-

1 mination. The Secretary may issue guidance to
2 describe the factors that will be used to deter-
3 mine under this subparagraph whether a peti-
4 tion is submitted with the primary purpose of
5 delaying the approval of an application.

6 “(C) EXHAUSTION OF ADMINISTRATIVE
7 REMEDIES.—

8 “(i) FINAL AGENCY ACTION WITHIN
9 180 DAYS.—The Secretary shall be consid-
10 ered to have taken final agency action on
11 a petition referred to in subparagraph (A)
12 if—

13 “(I) during the 180-day period
14 referred to in clause (ii) of such sub-
15 paragraph, the Secretary makes a
16 final decision within the meaning of
17 section 10.45(d) of title 21, Code of
18 Federal Regulations (or any successor
19 regulations); or

20 “(II) such period expires without
21 the Secretary having made such a
22 final decision, in which case the peti-
23 tion shall be deemed to have been de-
24 nied.

1 “(ii) DISMISSAL OF CERTAIN CIVIL
2 ACTIONS.—If a civil action is filed with re-
3 spect to a petition referred to in subpara-
4 graph (A) before final agency action within
5 the meaning of clause (i) has occurred, the
6 court shall dismiss the action for failure to
7 exhaust administrative remedies.

8 “(D) APPLICABILITY OF CERTAIN REGULA-
9 TIONS.—The provisions of this section are in
10 addition to the requirements for the submission
11 of a petition to the Secretary that apply under
12 section 10.30 or 10.35 of title 21, Code of Fed-
13 eral Regulations (or any successor regulations).

14 “(E) ANNUAL REPORT ON DELAYS IN AP-
15 PROVALS PER PETITIONS.—The Secretary shall
16 annually submit to the Congress a report that
17 specifies—

18 “(i) the number of applications under
19 this subsection that were approved during
20 the preceding 12-month period;

21 “(ii) the number of such applications
22 whose effective dates were delayed by peti-
23 tions referred to in subparagraph (A) dur-
24 ing such period; and

1 “(iii) the number of days by which the
2 applications were so delayed.

3 “(F) EXCEPTION.—This paragraph does
4 not apply to a petition that is made by the
5 sponsor of an application under this subsection
6 and that seeks only to have the Secretary take
7 or refrain from taking any form of action with
8 respect to that application.

9 “(G) DEFINITION.—For purposes of this
10 paragraph, the term ‘petition’ includes any re-
11 quest to the Secretary, without regard to
12 whether the request is characterized as a peti-
13 tion.

14 “(20) AUTHORIZATION OF APPROPRIATIONS.—
15 To carry out this subsection, there are authorized to
16 be appropriated such sums as may be necessary for
17 fiscal years 2010 and 2011.”.

18 (b) ADDITIONAL AMENDMENTS.—

19 (1) VENUE.—Section 1404 of title 28, United
20 States Code, is amended by adding at the end the
21 following:

22 “(e) VENUE IN CERTAIN PATENT INFRINGEMENT
23 DISPUTES.—

24 “(1) IN GENERAL.—In any action for patent in-
25 fringement brought by the holder or owner of the

1 patent pursuant to section 351(k)(18)(C) of the
2 Public Health Service Act, the defendant may move
3 to transfer the action to any other district in which
4 jurisdiction is proper.

5 “(2) TIMING.—The schedule applicable to a
6 motion under paragraph (1) is as follows:

7 “(A) A motion under paragraph (1) shall
8 be filed by the defendant no later than 45 days
9 after service of the complaint.

10 “(B) A response to such a motion, if any,
11 shall be filed no later than 20 days after service
12 of the motion.

13 “(C) A reply to such response, if any, shall
14 be filed no later than 10 days after service of
15 the response.

16 “(D) The schedule set forth in this para-
17 graph may be modified only by agreement of all
18 parties.

19 “(3) RESOLUTION.—When ruling on any mo-
20 tion filed under paragraph (2), the greatest weight
21 shall be given to the following factors:

22 “(A) The interest in identifying a district
23 court in which the case will be adjudicated ex-
24 peditiously.

1 “(B) The strong public interest in obtain-
2 ing prompt judicial resolution of patent dis-
3 putes so that the biological product which is the
4 subject of the patent dispute may be brought to
5 market as expeditiously as possible, consistent
6 with fair and prompt resolution of patent dis-
7 putes.

8 “(4) NO DELAY.—An action described in para-
9 graph (1) shall proceed as expeditiously as possible
10 while the court considers a motion under this sub-
11 section, and the court may not stay the proceedings
12 because a motion under this subsection has been
13 filed.”.

14 (2) PATENTS.—Section 271(e) of title 35,
15 United States Code, is amended—

16 (A) in paragraph (2)—

17 (i) by striking “or” at the end of sub-
18 paragraph (A);

19 (ii) by adding “or” at the end of sub-
20 paragraph (B);

21 (iii) by inserting after subparagraph
22 (B) the following:

23 “(C) a notice described in section
24 351(k)(18)(B) of the Public Health Service Act,

1 but only with respect to a patent identified in
2 such notice,”; and

3 (iv) in the matter following subpara-
4 graph (C) (as inserted by clause (iii) of
5 this subparagraph), by inserting before the
6 period the following: “, or if the notice de-
7 scribed in subparagraph (C) is provided in
8 connection with an application to obtain a
9 license to engage in the commercial manu-
10 facture, use, or sale of a biological product
11 claimed in a patent or the use of which is
12 claimed in a patent before the expiration of
13 such patent”;

14 (B) by adding at the end the following
15 paragraph:

16 “(6)(A) This paragraph applies in the case of
17 a patent—

18 “(i) which is disclosed in a response to a
19 request for patent information pursuant to sub-
20 paragraph (A) of section 351(k)(18) of the
21 Public Health Service Act;

22 “(ii) with respect to which a notice was
23 provided pursuant to subparagraph (B) of such
24 section; and

1 “(iii) for which an action for infringement
2 of the patent—

3 “(I) was brought after the expiration
4 of the 45-day period described in subpara-
5 graph (C) of such section; or

6 “(II) was brought before the expira-
7 tion of the 45-day period described in sub-
8 clause (I), but which was dismissed with-
9 out prejudice or was not prosecuted to
10 judgment in good faith.

11 “(B) In an action for infringement of a patent
12 described in subparagraph (A), the sole and exclu-
13 sive remedy that may be granted by a court, upon
14 a finding that the person who submitted the notice
15 described in subparagraph (A)(ii) infringed the pat-
16 ent, or that any person induced or contributed to in-
17 fringement of the patent, shall be a reasonable roy-
18 alty.

19 “(C) The owner or licensee of a patent that
20 should have been disclosed in response to a request
21 for patent information made by an applicant pursu-
22 ant to subparagraph (A) of section 351(k)(18) of
23 the Public Health Service Act, but that was not
24 timely disclosed under that subparagraph, may not

1 bring an action under this title for infringement of
2 that patent.”;

3 (C) in paragraph (5)—

4 (i) by adding “(A)” in front of
5 “Where”; and

6 (ii) by adding the following subpara-
7 graph:

8 “(B) Where a person has provided a notice
9 described in subparagraph (B) of section
10 351(k)(18) of the Public Health Service Act,
11 and neither the holder for the approved biologi-
12 cal product or the owner of a patent identified
13 in the notice brought an action for infringement
14 of such patent before the expiration of 45 days
15 after the date on which the notice was received,
16 the courts of the United States shall, to the ex-
17 tent consistent with the Constitution, have and
18 exercise subject matter jurisdiction in any ac-
19 tion brought by such person under section 2201
20 of title 28 for a declaratory judgement that
21 such patent is invalid or not infringed.”; and

22 (D) in paragraph (4), by striking “in para-
23 graph (2)” in both places it appears and insert-
24 ing “in subparagraphs (2)(A) or (2)(B)”.

25 (3) CONFORMING AMENDMENTS.—

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

5 (B) PUBLIC HEALTH SERVICE ACT.—Sub-
6 jection (j) of section 351 of the Public Health
7 Service Act (42 U.S.C. 262) is amended by in-
8 serting “or subsection (k)” after “subsection
9 (a)”.

10 (c) REVIEW OF APPLICATIONS SUBMITTED DURING
11 EXCLUSIVITY PERIODS.—

12 (1) USER FEE GOALS.—

13 (A) REVISION.—Within 180 days after the
14 date of the enactment of this Act, the Secretary
15 of Health and Human Services, in consultation
16 with the relevant stakeholders, shall revise the
17 PDUFA reauthorization performance goals and
18 procedures with respect to the user fee goals for
19 abbreviated biological product applications
20 under section 351(k) of the Public Health Serv-
21 ice Act, as added by subsection (a) of this sec-
22 tion, that are submitted more than 2 years in
23 advance of the expiration of any period of exclu-
24 sive marketing to which the reference drug is
25 entitled under subsection (k)(10) or subsection

1 (1) of section 351 of the Public Health Service
2 Act, as added by subsection (a) of this section
3 and section 4 respectively.

4 (B) CONSIDERATIONS.—In revising the
5 user fee goals for applications described in sub-
6 paragraph (A), the Secretary shall consider—

7 (i) the need to provide sufficient time
8 so that a decision on whether to approve
9 the application can be made in advance of
10 the expiration of any exclusivity, and con-
11 sidering the possibility that amendments
12 will be necessary after the initial decision
13 and prior to approval; and

14 (ii) the importance of conserving
15 agency resources.

16 (2) REVIEW PRIORITIES.—In setting priorities
17 with respect to the review of applications described
18 in paragraph (1)(A), the Secretary shall take into
19 account the number of years in advance of the expi-
20 ration of any exclusivity granted to the reference
21 drug that an application was submitted.

22 (3) SUBMISSION OF REVISED PERFORMANCE
23 GOALS TO CONGRESS.—The Secretary shall, within
24 30 days after revising the PDUFA reauthorization
25 performance goals and procedures under this sub-

1 section, submit to the Committee on Energy and
2 Commerce of the House of Representatives and the
3 Committee on Health, Education, Labor, and Pen-
4 sions of the Senate a letter describing the revised
5 goals and the basis for such revisions.

6 (4) DEFINITIONS.—In this subsection:

7 (A) The terms “abbreviated biological
8 product application” and “reference product”
9 have the meanings given to those terms in sec-
10 tion 351(i) of the Public Health Service Act, as
11 amended by section 2(a).

12 (B) The term “PDUFA reauthorization
13 performance goals and procedures” means the
14 performance goals and procedures of the Food
15 and Drug Administration, agreed to for pur-
16 poses of the reauthorization of part 2 of sub-
17 chapter C of chapter VII of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 279g et
19 seq.; relating to the prescription drug user fee
20 program) for fiscal year 2008 and succeeding
21 fiscal years.

22 **SEC. 4. PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS.**

23 Section 351 of the Public Health Service Act (42
24 U.S.C. 262), as amended by section 3, is further amended
25 by adding at the end the following:

1 “(1) PEDIATRIC STUDIES.—

2 “(1) APPLICATION OF CERTAIN PROVISIONS.—

3 The provisions of section 505A of the Federal Food,
4 Drug, and Cosmetic Act shall, except as inconsistent
5 with this section, apply to biological products ap-
6 proved under subsection (a) or (k) of this section to
7 the same extent and in the same manner as such
8 provisions apply to drugs approved under subsection
9 (c) or (j), respectively, of section 505 of the Federal
10 Food, Drug, and Cosmetic Act.

11 “(2) MARKET EXCLUSIVELY FOR NEW BIOLOGI-
12 CAL PRODUCTS.—If, prior to approval of an applica-
13 tion that is submitted under subsection (a) of this
14 section, the Secretary determines that information
15 relating to the use of a new biological product in the
16 pediatric population may produce health benefits in
17 that population, the Secretary makes a written re-
18 quest for pediatric studies (which shall include a
19 timeframe for completing such studies), the appli-
20 cant agrees to the request, such studies are com-
21 pleted using appropriate formulations for each age
22 group for which the study is requested within any
23 such timeframe, and the reports thereof are sub-
24 mitted and accepted in accordance with section

1 505A(d)(3) of the Federal Food, Drug, and Cos-
2 metic Act—

3 “(A) the period for such biological product
4 referred to in subparagraph (A) of subsection
5 (k)(10), including any extension under subpara-
6 graph (D) of such subsection, is extended by 6
7 months; and

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

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

1 and accepted in accordance with section 505A(d)(3)
2 of the Federal Food, Drug, and Cosmetic Act—

3 “(A) the period for such biological product
4 referred to in subparagraph (A) of subsection
5 (k)(10), including any extension under subpara-
6 graph (D) of such subsection, is extended by 6
7 months; and

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

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

○