

110TH CONGRESS
1ST SESSION

S. 1505

To amend the Public Health Service Act to provide for the approval of biosimilars, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 24, 2007

Mr. GREGG (for himself, Mr. BURR, and Mr. COBURN) 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 approval of biosimilars, 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 “Affordable Biologics
5 for Consumers Act”.

6 **SEC. 2. APPROVAL OF BIOSIMILARS.**

7 (a) IN GENERAL.—Section 351 of the Public Health
8 Service Act (42 U.S.C. 262) is amended—

(1) in subsection (j), by striking “under subsection (a)” and inserting “under subsection (a) or (k)”; and

(2) by adding at the end the following:

“(k) BIOSIMILARS.—

“(1) APPLICATION.—

“(A) SUBMISSION.—Any person may submit an application under this subsection for approval of a biologics license for a biosimilar.

“(B) DEFINITIONS.—In this subsection:

“(i) BIOSIMILAR.—The term ‘biosimilar’ means a biological product that, in an application submitted under this subsection, is claimed to be similar to a qualified biological product (in this subsection referred to as the ‘reference product’).

“(ii) QUALIFIED BIOLOGICAL PRODUCT.—The term ‘qualified biological product’ means a biological product that is a biotechnology-derived therapeutic biological product licensed under subsection (a) or a biotechnology-derived therapeutic protein product subject to an approved application that was submitted under section

1 505(b)(1) of the Federal Food, Drug, and
2 Cosmetic Act.

3 “(2) REVIEW AND APPROVAL OF BIOSIMILAR
4 APPLICATIONS.—

5 “(A) REVIEW.—An application submitted
6 under this subsection for a biosimilar shall be
7 reviewed—

8 “(i) by the division that was respon-
9 sible for review and approval of the ref-
10 erence product; and

11 “(ii) in accordance with the proce-
12 dures for review of biologics license appli-
13 cations established by the Secretary pursu-
14 ant to subsection (a)(2)(A).

15 “(B) APPROVAL.—The Secretary shall ap-
16 prove the application submitted under para-
17 graph (1) only if—

18 “(i) the applicant demonstrates that
19 the biosimilar conforms to the applicable
20 final product class-specific rule and, on the
21 basis of the data submitted in conformance
22 with such rule, the Secretary concludes the
23 product is safe, pure, and potent;

24 “(ii) the applicant demonstrates that
25 the biosimilar is as similar to the reference

1 product as may be achieved given the state
2 of scientific knowledge and technology ca-
3 pabilities at the time of submission of the
4 application;

5 “(iii) the applicant demonstrates that
6 the biosimilar has the same route of ad-
7 ministration, dosage form, mechanism of
8 action, and strength as the reference prod-
9 uct;

10 “(iv) the facility in which the bio-
11 similar is manufactured, processed,
12 packed, or held meets standards designed
13 to assure that the biological product con-
14 tinues to be safe, pure, and potent; and

15 “(v) the applicant (or other appro-
16 priate person) consents to the inspection of
17 the facility that is the subject of the appli-
18 cation, in accordance with subsection (c).

19 “(C) CONDITIONS OF APPROVAL.—The
20 Secretary may approve an application submitted
21 under paragraph (1) for a biosimilar—

22 “(i) only for indications for which the
23 reference product is approved;

24 “(ii) only if, with respect to each such
25 indication, the application conforms to the

1 applicable final product class-specific rule,
2 and on the basis of non-clinical and clinical
3 data submitted regarding such indication,
4 the Secretary concludes the product is
5 safe, pure, and potent; and

6 “(iii) only if the applicant agrees to
7 provide to the Secretary, on an ongoing
8 basis, all written documents it prepares for
9 any purpose (including any patent litigation)
10 that characterizes the difference between
11 the biosimilar and the reference
12 product.

13 “(3) REQUESTS FOR ISSUANCE OF PRODUCT
14 CLASS-SPECIFIC RULE.—

15 “(A) IN GENERAL.—Any person may submit
16 a request to the Secretary for the issuance
17 of a product class-specific rule applicable to a
18 qualified biological product and its class.

19 “(B) PRIORITY.—The Secretary—

20 “(i) in prioritizing among requests
21 under this paragraph for a rule, shall consider
22 likely market entry dates of
23 biosimilars and the amount of time that
24 will be needed to prepare the requested
25 product class-specific rule; and

1 “(ii) may summarily reject frivolous
2 or unsupported requests.

3 “(C) ISSUANCE OF RULE.—

4 “(i) IN GENERAL.—In response to a
5 request under this paragraph, the Sec-
6 retary shall carry out notice and comment
7 rulemaking procedures in accordance with
8 clause (ii).

9 “(ii) PROCEDURES.—To publish prod-
10 uct class-specific rules under this para-
11 graph, the Secretary shall, in response to
12 a request under this paragraph—

13 “(I) publish in the Federal Reg-
14 ister a concept paper setting forth the
15 specific questions to be addressed in
16 the product class-specific rule and in-
17 vite comments on the concept paper
18 from any interested persons;

19 “(II) accept comments on the
20 concept paper for not less than 4
21 months;

22 “(III) consider the public com-
23 ments on the concept paper;

24 “(IV) publish in the Federal Reg-
25 ister the proposed product class-spe-

1 cific rule and invite comments on the
2 proposed rule from any interested per-
3 sons;

4 “(V) accept comments on the
5 proposed rule for not less than 6
6 months;

7 “(VI) obtain the advice of the
8 Biosimilars Advisory Committee with
9 respect to the proposed rule; and

10 “(VII) except as provided in sub-
11 paragraph (D), not later than 2 years
12 after receipt of the initial request,
13 publish in the Federal Register the
14 final product class-specific rule or a
15 determination that, given the current
16 state of scientific and technical knowl-
17 edge, it is not feasible to issue a prod-
18 uct class-specific rule setting forth
19 data that will ensure the safety, pu-
20 rity, and potency of biosimilars to be
21 covered by the rule.

22 “(iii) REPORT TO CONGRESS.—If the
23 Secretary determines under clause (ii)(VII)
24 that it is not feasible to issue the final
25 class-specific rule in the 2-year period fol-

1 lowing the date of the applicable initial re-
2 quest, the Secretary shall submit to Con-
3 gress a report that describes why Secretary
4 was unable to issue such final rule and the
5 plan and timeline of the Secretary for
6 issuing such final rule.

7 “(D) CONSOLIDATION OF REQUESTS.—The
8 Secretary may consolidate requests submitted
9 under this paragraph that refer to closely re-
10 lated products or product classes. If the Sec-
11 retary chooses to consolidate such requests, the
12 Secretary shall publish the final product class-
13 specific rule or a determination described in
14 subparagraph (C)(ii)(VII) not later than 30
15 months after receipt of the first request for a
16 rule for any product in the class.

17 “(4) PRODUCT CLASS-SPECIFIC RULES.—

18 “(A) IN GENERAL.—A rule published
19 under paragraph (3) shall describe the data and
20 information that will be required in an applica-
21 tion submitted under paragraph (1).

22 “(B) REQUIRED ELEMENTS.—At a min-
23 imum, a rule published under paragraph (3)
24 shall require—

1 “(i) data demonstrating the consist-
2 ency and robustness of the manufacturing
3 process for the active ingredient or active
4 ingredients of the biosimilar and the fin-
5 ished formulation of the biosimilar;

6 “(ii) data demonstrating the stability,
7 compatibility (such as with excipients), and
8 biological and physicochemical integrity of
9 the active ingredient or active ingredients
10 of the biosimilar;

11 “(iii) data from physical, chemical,
12 and biological assays fully characterizing
13 the biosimilar, in comparison with the ref-
14 erence product, at both the active ingre-
15 dient or active ingredients and finished
16 product levels;

17 “(iv) data from comparative nonclin-
18 ical studies demonstrating that the bio-
19 similar and the reference product have
20 similar profiles in terms of pharmaco-
21 kinetics, pharmacodynamics, toxicity,
22 immunogenicity, and other relevant fac-
23 tors;

24 “(v) data from comparative clinical
25 trials demonstrating that the biosimilar

1 and the reference product have similar pro-
2 files in terms of safety, purity, and po-
3 tency, including pharmacokinetic studies,
4 pharmacodynamic studies, immunogenicity
5 studies, and trials of sufficient size and du-
6 ration to demonstrate that the products
7 are similar in their safety (in terms of na-
8 ture, seriousness, and frequency of adverse
9 reactions), purity, and potency profiles;
10 and

11 “(vi) data regarding postmarket as-
12 sessment and monitoring of safety, purity,
13 and potency, including, as appropriate,
14 clinical trials, tests to investigate
15 immunogenicity, patient registries, and
16 other surveillance measures.

17 “(5) REVISIONS TO RULES.—If a new condition
18 of use is approved for a reference product after the
19 latest publication of the final product class-specific
20 rule applicable to such product, the Secretary shall
21 promptly update and republish the rule in accord-
22 ance with paragraphs (3) and (4) (irrespective of
23 whether a request for such revision has been re-
24 ceived under paragraph (3)(A)) to address the data
25 and information that will be required in an applica-

1 tion under this subsection for approval of the new
2 condition of use. The requirements of paragraph
3 (2)(C) shall apply if the new condition of use is a
4 new indication.

5 “(6) BIOSIMILARS ADVISORY COMMITTEE.—

6 “(A) ESTABLISHMENT.—The Secretary
7 shall establish a Biosimilars Advisory Com-
8 mittee (in this paragraph referred to as the
9 ‘Committee’).

10 “(B) DUTIES.—The Committee shall—

11 “(i) provide expert scientific advice
12 and recommendations to the Secretary re-
13 garding the development and approval of
14 biosimilars; and

15 “(ii) in formulating such advice and
16 recommendations, provide interested per-
17 sons with a reasonable opportunity to
18 make written and oral presentations.

19 “(C) MEMBERSHIP.—

20 “(i) QUALIFICATIONS.—The Secretary
21 shall appoint to serve on the Committee in-
22 dividuals with expertise on therapeutic bio-
23 logical products, including manufacturing,
24 safety, effectiveness, and other relevant
25 matters. The Secretary shall ensure that

1 the Committee consists of members with
2 adequately diversified expertise and prac-
3 tical experience in such fields as clinical
4 medicine, biological and physical sciences,
5 pharmacoepidemiology and postmarket
6 safety surveillance, and related professions.

7 “(ii) NOMINATIONS.—In appointing
8 members of the Committee, the Secretary
9 shall provide an opportunity for scientific,
10 industry, and consumer organizations and
11 the public to nominate such members.

12 “(iii) NONVOTING MEMBERS.—The
13 Committee shall include, as nonvoting
14 members, representatives of patient organi-
15 zations, manufacturers of innovative bio-
16 logical products, and manufacturers of
17 biosimilars.

18 “(iv) SUPPLEMENTAL MEMBER-
19 SHIP.—For the purpose of developing a
20 product class-specific rule under para-
21 graphs (3) and (4), the Secretary may sup-
22 plement the membership of the Committee,
23 or arrange for advice from another advi-
24 sory committee, in order to obtain the ad-

1 vice of individuals with special expertise re-
2 lating to any product under review.

3 “(7) TIME FRAMES FOR APPLICATION AND AU-
4 THORIZATION.—

5 “(A) SUBMISSION OF APPLICATIONS.—No
6 application for a biosimilar may be submitted
7 under this subsection unless—

8 “(i) the Secretary has published under
9 paragraph (3) a final product class-specific
10 rule applicable to the reference product;
11 and

12 “(ii) not less than 12 years have
13 elapsed from the date on which the ref-
14 erence product was approved or licensed.

15 “(B) EFFECTIVE DATE OF APPROVAL.—
16 Subject to subparagraph (C), approval of an
17 application submitted under paragraph (1) shall
18 not be made effective until at least 14 years
19 have elapsed from the date on which the ref-
20 erence product was approved or licensed.

21 “(C) SIGNIFICANT CLINICAL BENEFIT.—
22 Approval of an application submitted under
23 paragraph (1) shall not be made effective until
24 at least 16 years have elapsed from the date on

1 which the reference product was approved or li-
2 censed if—

3 “(i) during the 12-year period fol-
4 lowing the approval or licensing of the ref-
5 erence product, the Secretary approves a
6 supplement to the new drug or biologics li-
7 cense application for the reference product
8 that seeks approval to market the ref-
9 erence product for a new indication; and

10 “(ii) in the opinion of the Secretary,
11 the new indication provides a significant
12 clinical benefit.

13 “(D) SUPPLEMENT APPLICATION OF REF-
14 ERENCE PRODUCT.—If, at any time following
15 approval of the reference product, the holder of
16 the approved reference product application sub-
17 mits a supplemental application with new clin-
18 ical data (other than bioavailability data) to
19 support a new condition of use (other than a
20 new indication with a significant clinical benefit
21 approved during the first 12 years after initial
22 product approval), and those data are essential
23 to approval of the supplemental application, the
24 Secretary may not approve an application for a

1 biosimilar for the new condition of use for 3
2 years following approval of the supplement.

3 “(E) EXCLUSIVE APPROVAL PATHWAY.—
4 The Secretary may not approve, under any
5 other provision of law, a product that is claimed
6 to be similar to or the same as a reference
7 product.

8 “(F) APPROVAL OF BIOSIMILAR APPLICA-
9 TION WITH RESPECT TO OLDER REFERENCE
10 PRODUCTS.—Notwithstanding any other provi-
11 sion of this subsection, an application submitted
12 under paragraph (1) that relies on a reference
13 product approved more than 14 years before
14 the date of enactment of this subsection may be
15 made effective on the date that is the later of—

16 “(i) the publication of a product class-
17 specific rule under paragraph (3) in which
18 the reference product is included; or

19 “(ii) 1 year after the date of enact-
20 ment of this subsection.

21 “(G) TRANSITION.—If, during the period
22 following the approval of a reference product
23 that was approved more than 14 years before
24 the date of enactment of this subsection but be-
25 fore the publication of a product class-specific

1 rule under paragraph (3) in which the reference
2 product is included, the holder of the approved
3 reference product application obtains approval
4 of a new indication with a significant clinical
5 benefit as determined by the Secretary, ap-
6 proval of an application submitted under para-
7 graph (1) that relies on such reference product
8 may not be made effective under 16 years after
9 the date of approval of the reference product.

10 “(8) PATENT NOTIFICATIONS AND LINKAGES.—

11 “(A) NOTIFICATION.—When an application
12 for a biosimilar is submitted, the Secretary
13 shall publish a notice in the Federal Register
14 identifying—

15 “(i) the sponsor of the application of
16 the reference product upon which the ap-
17 plication for the biosimilar relies; and

18 “(ii) the name of the sponsor of the
19 application for the biosimilar, or an agent
20 designated by such sponsor to receive com-
21 munications regarding patents.

22 “(B) INFORMATION FROM PATENT HOLD-
23 ER.—

24 “(i) IN GENERAL.—A patent owner
25 may—

1 “(I) request information from the
2 person that submits an application for
3 a biosimilar under paragraph (1) to
4 ascertain whether such person’s prod-
5 uct or processes would infringe on a
6 patent of the patent owner;

7 “(II) provide such person or its
8 designee a notice of patents that may
9 be infringed by the production or sale
10 of the biosimilar, such as patents on
11 compound (protein sequence), com-
12 position, host cell, nucleic acid, proc-
13 ess of production, and method of
14 treatment patents; or

15 “(III) indicate with such notifica-
16 tion whether the patent holder is open
17 to licensing the patent rights on a
18 non-exclusive basis.

19 “(ii) NO DECLARATORY JUDGMENT.—
20 A patent designated as available for licen-
21 sure pursuant to clause (i)(III) may not be
22 the subject of a declaratory judgment ac-
23 tion brought by the biosimilar applicant
24 prior to approval of the application for a
25 biosimilar under this subsection.

“(C) WRITTEN EXPLANATION.—

“(i) IN GENERAL.—A person that submits an application for approval of a biosimilar under this subsection that requests approval prior to the expiration of a patent identified by a patent owner shall provide to such patent owner, a written explanation of—

“(I) why the patent identified in subparagraph (B)(i) would not be infringed by the approval of the application for the biosimilar; or

“(II) why the identified patent is invalid.

“(ii) COMPLIANCE.—With respect to process of manufacture patents, the biosimilar applicant must comply with the requirements of section 295 of title 35, United States Code.

“(D) APPROVAL DATE.—Approval of an application for a biosimilar submitted under this subsection may be effective on the applicable date described in paragraph (7) even if patent litigation has not concluded. If a patent is found valid and infringed before approval of the

1 application for a biosimilar, and the patent ex-
2 pires after the applicable effective date of the
3 biosimilar application described in paragraph
4 (7), approval of the biosimilar application may
5 not be effective until the expiration of the in-
6 fringed patent.

7 “(E) DECLARATORY JUDGMENT ACTION.—

8 A person that submits an application for a bio-
9 similar under this subsection may not com-
10 mence a declaratory judgment action con-
11 cerning a patent identified in subparagraph
12 (B)(i) later than 18 months before the applica-
13 ble effective date of the biosimilar application
14 described in paragraph (7), or the date that is
15 60 days after providing the written explanation
16 in subparagraph (C) of this paragraph, if such
17 provision occurs during the 18-month period be-
18 fore the applicable effective date of the bio-
19 similar application described in paragraph (7).

20 “(9) EXCLUSIVITY OF BIOSIMILARS.—The Sec-

21 retary may not approve an application for a bio-
22 similar that relies on a reference product for 1 year
23 after the date of approval of the first biosimilar ap-
24 plication that relies on such reference product.

25 “(l) PROPER NAME.—For purposes of this section:

1 “(1) BIOTECHNOLOGY-DERIVED THERAPEUTIC
2 PROTEINS.—

3 “(A) IN GENERAL.—Subject to subpara-
4 graph (D), the term ‘proper name’, with respect
5 to a biotechnology-derived therapeutic protein,
6 means—

7 “(i) the name adopted for such pro-
8 tein by the United States Adopted Names
9 Council if such name is a unique USAN;
10 or

11 “(ii) if the biotechnology-derived
12 therapeutic protein lacks a unique USAN,
13 an official name designated pursuant to
14 subparagraph (C).

15 “(B) UNIQUE USAN.—The term ‘unique
16 USAN’, with respect to a biotechnology-derived
17 therapeutic protein, means a name adopted for
18 such protein by the United States Adopted
19 Names Council that has not been adopted for
20 any protein manufactured by a different person.

21 “(C) DESIGNATION.—The Secretary shall
22 designate an official name for any bio-
23 technology-derived therapeutic protein that
24 lacks a unique USAN. Any official name des-
25 ignated under this subparagraph shall be the

1 only official name of that protein used in any
2 official compendium published after such name
3 has been designated. In no event, however, shall
4 the Secretary designate an official name so as
5 to infringe a valid trademark. Any designation
6 under this subparagraph shall be made by rule
7 in accordance with section 553 of title 5,
8 United States Code.

9 “(D) EXCEPTION.—The term ‘proper
10 name’, with respect to a biotechnology-derived
11 therapeutic protein that was licensed by the
12 Secretary prior to the effective date of the Af-
13 fordable Biologics for Consumers Act, means
14 the name adopted for such protein by the
15 United States Adopted Names Council, irre-
16 spective of whether such name is a unique
17 USAN.

18 “(2) OTHER BIOLOGICAL PRODUCTS.—The
19 term ‘proper name’, with respect to a biological
20 product that is not a biotechnology-derived thera-
21 peutic protein, means—

22 “(A) the official name designated by the
23 Secretary for such biological product pursuant
24 to section 508 of the Federal Food, Drug, and
25 Cosmetic Act;

1 “(B) if there is no such official name and
2 such biological product is an article recognized
3 in an official compendium, the official title
4 thereof in such compendium; or

5 “(C) if neither subparagraph (A) nor sub-
6 paragraph (B) applies, the common or usual
7 name, if any, of such biological product.

8 “(m) INTERCHANGEABILITY.—

9 “(1) IN GENERAL.—

10 “(A) NO DESIGNATION OF INTERCHANGE-
11 ABILITY OR THERAPEUTIC EQUIVALENCE.—The
12 Secretary may not designate a biosimilar as
13 interchangeable with (or therapeutically equiva-
14 lent to) the applicable reference product.

15 “(B) ASSESSMENT.—Not later than 2
16 years after the date of enactment of this sub-
17 section, and every 2 years thereafter, the Sec-
18 retary shall assess the state of scientific and
19 technical knowledge regarding the ability of the
20 Food and Drug Administration to make a de-
21 termination that a biosimilar is interchangeable
22 with (or therapeutically equivalent to) a ref-
23 erence product on a product class basis.

24 “(2) DETERMINATION.—If the Secretary finds
25 that the state of scientific and technical knowledge

1 enables the Food and Drug Administration to make
 2 a determination of interchangeability (or therapeutic
 3 equivalence) with respect to 1 or more product class-
 4 es, then the Secretary shall submit a report to Con-
 5 gress that describes such findings and recommenda-
 6 tions for statutory criteria that should govern such
 7 a determination.”.

8 (b) CONFIDENTIALITY.—Subsection (j) of section
 9 351 of the Public Health Service Act (42 U.S.C. 262),
 10 as amended by subsection (a)(1), is further amended by
 11 adding at the end the following: “The Secretary shall
 12 maintain the confidentiality of information submitted
 13 under this section for a biological product to the same ex-
 14 tent and in the same manner as the Secretary maintains
 15 the confidentiality of information submitted under section
 16 505 of the Federal Food, Drug, and Cosmetic Act for a
 17 drug.”.

18 (c) PATENT ACTIONS.—

19 (1) INFRINGEMENT ACTION.—Section 271(e)(2)
 20 of title 35, United States Code, is amended—

21 (A) in subparagraph (A), by striking “,
 22 or” and inserting a comma;

23 (B) in subparagraph (B), by striking “pat-
 24 ent,” and inserting “patent, or”; and

1 (C) by adding after subparagraph (B) the
 2 following:

3 “(C) a written explanation described in
 4 section 351(k)(8)(C)(i) of the Public Health
 5 Service Act,”.

6 (2) PATENT TERM AUTHORITY.—Section
 7 156(b) of title 35, United States Code, is amended
 8 by adding at the end before the period, the fol-
 9 lowing: “, and shall extend to any product that is
 10 the subject of an application approved under section
 11 351(k) of the Public Health Service Act”.

12 **SEC. 3. AMENDMENTS TO FEDERAL FOOD, DRUG, AND COS-**
 13 **METIC ACT.**

14 (a) LABELING.—

15 (1) UNIQUE NAME.—Section 502 of the Federal
 16 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is
 17 amended by adding at the end the following:

18 “(y) If it is a biotechnology-derived therapeutic pro-
 19 tein, it was licensed under section 351 of the Public
 20 Health Service Act prior to the effective date of the Af-
 21 fordable Biologics for Consumers Act, it lacks a unique
 22 USAN, and its labeling fails to bear (i) its proper name
 23 (as defined in section 351(l) of the Public Health Service
 24 Act); (ii) its brand name or phrasing, approved by the Sec-
 25 retary, that adequately distinguishes it from other ap-

1 proved biotechnology-derived therapeutic proteins with the
2 same proper name; and (iii) the following warning: ‘Any
3 change in _____, including a change
4 in manufacturer, should be made cautiously and only if
5 authorized by and supervised by the prescribing health
6 care professional.’, with the proper name of the product
7 being inserted in the blank space. The requirement in the
8 preceding sentence regarding the inclusion of a warning
9 applies beginning on the date that is 180 days after the
10 date of the enactment of the Affordable Biologics for Con-
11 sumers Act.

12 “(z) If it is a biotechnology-derived therapeutic pro-
13 tein not subject to paragraph (y), and its labeling fails
14 to include (i) its proper name (as defined in section 351(l)
15 of the Public Health Service Act); and (ii) the following
16 warning: ‘This product shall not be dispensed in substi-
17 tution for another biological product that was prescribed
18 to be dispensed, unless such substitution was expressly au-
19 thorized by and is supervised by the prescribing health
20 care professional.’. In the case of such a protein that is
21 a biosimilar licensed under section 351(k) of the Public
22 Health Service Act, the warning required by the preceding
23 sentence shall read as follows: ‘This product shall not be
24 dispensed in substitution for another biological product
25 that was prescribed to be dispensed including

1 _____.’, with the proprietary name and
2 proper name of the reference product being inserted in the
3 blank space.

4 “(aa) If it is a biosimilar approved under section
5 351(k) of the Public Health Service Act and the labeling—

6 “(1) is inconsistent with the labeling of the ref-
7 erence product (as referred to in such section
8 351(k));

9 “(2) does not accurately characterize the bio-
10 similar or account for any differences between the
11 biosimilar and the reference product;

12 “(3) does not describe any new data submitted
13 in support of approval of the biosimilar since the
14 date of approval of the reference product;

15 “(4) does not disclose any special safety con-
16 cerns identified with respect to the biosimilar; or

17 “(5) omits any safety information, such as ad-
18 verse events, that are identified with respect to, and
19 included in the labeling of, the reference product,
20 unless sponsor of such biosimilar justifies such omis-
21 sion to the Secretary.”.

22 (b) DISPENSING.—Section 503(b) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) is
24 amended by adding at the end the following:

1 “(6) A drug that is subject to paragraph (1) and is
 2 a biotechnology-derived therapeutic protein licensed under
 3 section 351 of the Public Health Service Act shall not be
 4 dispensed unless the prescription specifies the drug’s pro-
 5 prietary name or, if the drug lacks a proprietary name,
 6 the drug’s proper name (as defined in section 351(l) of
 7 such Act). The act of dispensing a drug contrary to the
 8 preceding sentence shall be deemed to be an act which re-
 9 sults in the drug being misbranded while held for sale.”.

10 **SEC. 4. REPORT TO CONGRESS.**

11 Not later than 2 years after the date of the enact-
 12 ment of this Act, and every 2 years thereafter, the Sec-
 13 retary of Health and Human Services shall submit a re-
 14 port to the Congress making recommendations on whether
 15 it is feasible, in the state of scientific and technical knowl-
 16 edge (as of the date of such report), to approve applica-
 17 tions under section 351(k) of the Public Health Service
 18 Act, as added by section 2 of this Act, for biological prod-
 19 ucts that are claimed to be similar to vaccines, blood or
 20 plasma products or their derivatives, gene therapy, cell
 21 processing, naturally derived therapeutic proteins, or other
 22 biological products that do not contain biotechnology-de-
 23 rived therapeutic proteins as any active ingredient.

○