SEC. 1. ESTABLISHING A NEW ABBREVIATED LICENSURE PATHWAY FOR BIOLOGICAL PRODUCTS.

(a) In General.—Section 351(a) of the Public Health Service Act (21 U.S.C. 262(a)) is amended by adding at the end the following:

"(4)(A) Any person may submit an application under this paragraph for licensure of a biological product under this subsection that relies, in whole or in part, on—

"(i) the Secretary's determination of safety, purity, or potency or safety or efficacy with respect to one or more previously approved drug products;

"(ii) published literature; or

"(iii) a combination of information described in clauses (i) and (ii).

"(B)(i) The Secretary shall approve a biological product license application submitted under this paragraph if—

"(I) the application includes adequate information to demonstrate that reliance on the information described in subparagraph (A) is scientifically appropriate; and

"(II) the biological product meets the requirement of paragraph (2)(C).

"(ii) In making a determination under clause (i), the Secretary may consider, with respect to both the biological product that is the subject to the application under this paragraph and the previously approved drug product on which such application relies, the level of characterization, the extent to which the mechanism of action is known, the relative complexity, and any other information as the Secretary determines appropriate.

"(C)(i) The Secretary may indicate through guidance that the science and experience, as of the date of such guidance, with respect to a particular previously approved drug product or a biological product class or drug class does not allow for approval of an application for a license submitted under this paragraph.

"(ii) The Secretary may issue a subsequent guidance to modify or reverse any guidance issued under clause (i).

"(iii) Clause (i) shall not be construed to require the Secretary to approve an application with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

"(D)(i) Approval of an application submitted under this paragraph may not be made effective by the Secretary until the expiration of any applicable exclusivity under subsection (k)(7) of this section or section 505(c)(3)(E), 505(j)(5)(F), 505A, 505E, or 527 of the Federal Food, Drug, and Cosmetic Act of the previously approved drug product upon which the application under subparagraph (A) relies.

"(ii) An application under this paragraph that relies on a previously approved drug product that was licensed under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the application for such product was first licensed under this subsection.

"(E) Subsection (k)(7) shall not apply with respect to a biological product that is the subject of

an application approved under this paragraph.

"(F)(i) Nothing in this paragraph shall preclude submission of an application under this subsection other than an application described in subparagraph (A) that the Secretary determines would otherwise be appropriate for such submission, including any application that does not rely on the Secretary's determination of safety, purity, and potency for a biological product that has been licensed under this subsection or upon the Secretary's determination of safety and efficacy of a drug approved under section 505. The Secretary shall issue guidance describing what constitutes such reliance and describing the applications that should be appropriately submitted under this paragraph. The issuance (or non-issuance) of guidance shall not preclude the review of, or action on, an application appropriately submitted under this paragraph.

"(ii) Nothing in this paragraph shall preclude the submission or approval of an application for licensure of a biological product under this subsection, including an application not described in this paragraph, or under subsection (k), that relies on published literature.".

(b) Conforming Amendments.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (i)—

(A) in paragraph (4), by inserting "(including a biological product licensed pursuant to an application under subsection (a)(4))" after "subsection (a)"; and

(B) by adding at the end the following:

"(5) The term 'previously approved drug product' means a drug for which there is in effect an approved license under subsection (a) or an approved application under section 505(c) of the Federal Food, Drug, and Cosmetic Act, with respect to which the Secretary's finding of safety, purity, or potency, or finding of safety and efficacy, is relied on to support a demonstration under subsection (a)(2)(C)(i)(I) that the biological product that is the subject of an application submitted under subsection (a)(4) is safe, pure, and potent.".

(2) in subsection (k)(7)—

(A) in subparagraph (A), by inserting "(except for a license issued under subsection (a)(4))" before the period; and

(B) in subparagraph (B), by inserting "(except for a license issued under subsection (a)(4))" before the period;

(3) in subsection (l)—

(A) in paragraph (1)—

(i) in the paragraph heading, insert "OR SUBSECTION (A)(4) APPLICATION" after "SUBSECTION (K) APPLICATION";

(ii) in subparagraph (A)—

(I) by inserting "or under subsection (a)(4) (referred to in this subsection as the 'subsection (a)(4) applicant')" after "subsection (k) applicant")"; and

(II) by inserting "or the sponsor of the previously approved drug product (referred to in this subsection as the 'previously approved drug product sponsor')" after "sponsor")"; and

(iii) in subparagraph (B)—

(I) in clause (ii), by inserting before the period in each of subclauses (I) and (II) the following: "or previously approved drug product"; and

(II) in clause (iii), by inserting "or previously approved drug product, as applicable" after "with respect to the reference product";

(B) in the heading of paragraph (2), by inserting "AND SUBSECTION (A)(4)" before "APPLICATION";

(C) in paragraph (3)—

(i) in subparagraph (A)(ii), by inserting "or that the previously approved drug product sponsor would be prepared to license to the subsection (a)(4) applicant, as applicable" before the period; and

(ii) in the heading of subparagraph (B), by inserting "OR SUBSECTION (A)(4) APPLICANT" after "SUBSECTION (K) APPLICANT";

(D) in paragraph (4)—

(i) by amending subparagraph (A) to read as follows:

"(A) IN GENERAL.—After receipt by the subsection (k) applicant or the subsection (a)(4) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant, or the previously approved drug product sponsor and the subsection (a)(4) applicant, shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant, the reference product sponsor, the subsection (a)(4) applicant, or the previously approved drug product sponsor shall be the subject of an action for patent infringement under paragraph (6)."; and

(ii) in subparagraph (B)—

(I) by inserting ", or the previously approved drug product sponsor and the subsection (a)(4) applicant," before "fail to agree"; and

(II) by striking "or the reference product sponsor" and inserting ", the reference product sponsor, the subsection (a)(4) applicant, or the previously approved drug product sponsor";

(E) in paragraph (5)—

(i) in subparagraph (A)—

(I) by inserting ", or the subsection (a)(4) applicant shall notify the previously approved drug product sponsor," before "of the number"; and

(II) by striking "to the reference product sponsor" and inserting "to such sponsor"; and

(ii) in subparagraph (B)—

(I) in clause (i)—

(aa) in the matter preceeding subclause (I)—

(AA) by inserting “or by the subsection (a)(4) applicant and the previously approved drug product sponsor,” before “but in no case”; and

(BB) by striking “the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor” and inserting “such applicant notifies such sponsor under subparagraph (A), such applicant and such sponsor”;

(bb) in subclause (I), by inserting “or the subsection (a)(4) applicant” after “subsection (k) applicant”; and

(cc) in subclause (II), by inserting “or the previously approved drug product sponsor” after “reference product sponsor”; and

(II) in clause (ii)—

(aa) in the clause heading, by inserting “OR PREVIOUSLY APPROVED DRUG PRODUCT SPONSOR” after “REFERENCE PRODUCT SPONSOR”;

(bb) by inserting “or the previously approved drug product sponsor” after “reference product sponsor” each place such term appears; and

(cc) by inserting “or subsection (a)(4) applicant” after “subsection (k) applicant” each place such term appears;

(F) in paragraph (6)(A)—

(i) by inserting “, or the subsection (a)(4) applicant and the previously approved drug product sponsor,” before “on patents”; and

(ii) by inserting “or the previously approved drug product sponsor” before “shall bring”;

(G) in paragraph (7)—

(i) in subparagraph (A), by inserting “or the previously approved drug product sponsor provided the list to the subsection (a)(4) applicant,” before “under paragraph (3)(A)”;

(ii) in subparagraph (B), by inserting “or the previously approved drug product sponsor” after “reference product sponsor” each place such term appears; and

(iii) in the flush text following subparagraph (B)—

(I) by inserting “, or the previously approved drug product sponsor shall provide to the subsection (a)(4) applicant,” before “a supplement to the list”;

(II) by inserting “or the previously approved drug product sponsor” before “under paragraph (3)(A)”; and

(III) by inserting “, or the subsection (a)(4) applicant shall provide a statement to the previously approved drug product sponsor,” before “in accordance with”;

(H) in paragraph (8)—

(i) in subparagraph (A), by inserting ", or the subsection (a)(4) applicant shall provide notice to the previously approved drug product sponsor," before ", not later than"; and

(ii) in subparagraph (C)—

(I) by inserting "or the previously approved drug product sponsor" before "has sought"; and

(II) by inserting ", or the previously approved drug product sponsor and the subsection (a)(4) applicant," after "subsection (k) applicant";

(I) in paragraph (9)—

(i) in subparagraph (A)—

(I) in the subparagraph heading, by inserting "OR SUBSECTION (A)(4) APPLICATION" after "APPLICATION";

(II) by inserting "or subsection (a)(4) applicant" before "provides the application and"; and

(III) by striking "neither the reference product sponsor nor the subsection (k) applicant" and inserting "neither the reference product sponsor or the previously approved drug product sponsor nor the subsection (k) applicant or the subsection (a)(4) applicant";

(ii) in the heading of subparagraph (B), by inserting "OR SUBSECTION (A)(4) APPLICANT" after "APPLICANT"; and

(iii) in the heading of subparagraph (C), by inserting "OR SUBSECTION (A)(4) APPLICATION" after "APPLICATION";

(J) by inserting "or subsection (a)(4) application" after "subsection (k) application" each place such term appears;

(K) by inserting "or subsection (a)(4) applicant" after "subsection (k) applicant" each place such term appears, other than paragraphs (1)(A), (3)(A)(ii), (4), (5), (6)(A), (7), (8)(A), (8)(C), and (9)(A); and

(L) by inserting "or the previously approved drug product sponsor" after "reference product sponsor" each place such term appears, except in paragraphs (1)(A), (3)(A)(ii), (4), (5), (6)(A), (7), (8)(A), (8)(C), and (9)(A); and

(4) in subsection (m)—

(A) in paragraph (2)—

(i) by inserting "or subsection (a)(4)" after "that is submitted under subsection (a)";

(ii) in subparagraph (A), by striking "; and" and inserting a semicolon; and

(iii) by striking the period in subparagraph (B) and inserting "; and"; and

(iv) by adding at the end the following:

"(C) the period for such biological product referred to in subsection (a)(4)(E)(ii) is

deemed to be 4 years and 6 months rather than 4 years.”; and

(B) in paragraph (3)—

(i) in subparagraph (A), by striking “; and” and inserting a semicolon;

(ii) by striking the period in subparagraph (B) and inserting “; and”; and

(iii) by adding at the end the following:

“(C) the period for such biological product referred to in subsection (a)(4)(E)(ii) is deemed to be 4 years and 6 months rather than 4 years.”.