"(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States related to the activities required under this section.".

(b) REPORT TO CONGRESS.—Not later than 3 years after the date of enactment of this Act, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the status of implementing the requirements of section 1926 of the Public Health Service Act (42 U.S.C. 300x–26), as amended by subsection (a), and a description of any technical assistance provided under subsection (e) of such section, including the number of meetings requested and held related to technical assistance.

(c) CONFORMING AMENDMENT.—Section 212 of division D of the Consolidated Appropriations Act, 2010 (Public Law 111–117) is repealed.

SEC. 605. BIOLOGICAL PRODUCT DEFINITION.

Section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)) is amended by striking "(except any chemically synthesized polypeptide)".

SEC. 606. PROTECTING ACCESS TO BIOLOGICAL PRODUCTS.

Section 351(k)(7) of the Public Health Service Act (42 U.S.C. 262(k)(7)) is amended by adding at the end the following:

"(D) DEEMED LICENSES.—

"(i) NO ADDITIONAL EXCLUSIVITY THROUGH DEEMING.—An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

"(ii) APPLICATION OF LIMITATIONS ON EXCLUSIVITY.—Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

"(iii) APPLICABILITY.—The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.".

SEC. 607. STREAMLINING THE TRANSITION OF BIOLOGICAL PRODUCTS.

Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) is amended—

(1) by striking "An approved application" and inserting the following:

"(A) IN GENERAL.—An approved application"; and

(2) by adding at the end the following:

"(B) TREATMENT OF CERTAIN APPLICATIONS.—

"(i) IN GENERAL.—With respect to an application for a biological product submitted under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is filed not later than March 23, 2019, and is not approved as of March 23, 2020, the Secretary shall continue to review such application under such section 505 after March 23, 2020.

"(ii) EFFECT ON LISTED DRUGS.—Only for purposes of carrying out clause (i), with respect to any applicable listed drug with respect to such application, the following shall apply:

"(I) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i), shall continue to be identified as a listed drug on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and the information for such drug on such list shall not be revised after March 20, 2020, until—

"(aa) such drug is removed from such list in accordance with subclause (III) or subparagraph (C) of such section 505(j)(7); or

"(bb) this subparagraph no longer has force or effect.

"(II) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i) shall be subject only to requirements applicable to biological products licensed under such section.

"(III) Upon approval under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act of an application described in clause (i), the Secretary shall remove from the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act any listed drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act pursuant to subparagraph (A) and that is referenced in such approved application, unless such listed drug is referenced in one or more additional applications described in clause (i).

"(iii) DEEMED LICENSURE.—Upon approval of an application described in clause (i), such approved application shall be deemed to be a license for the biological product under section 351 of the Public Health Service Act.

"(iv) RULE OF CONSTRUCTION.—

"(I) APPLICATION OF CERTAIN PROVISIONS.—

"(aa) PATENT CERTIFICATION OR STATEMENT.—An application described in clause (i)

shall contain a patent certification or statement described in, as applicable, section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act or clauses (vii) and (viii) of section 505(j)(2)(A) of such Act and, with respect to any listed drug referenced in such application, comply with related requirements concerning any timely filed patent information listed pursuant to section 505(j)(7) of such Act.

"(bb) DATE OF APPROVAL.—The earliest possible date on which any pending application described in clause (i) may be approved shall be determined based on—

"(AA) the last expiration date of any applicable period of exclusivity that would prevent such approval and that is described in section 505(c)(3)(E), 505(j)(5)(B)(iv), 505(j)(5)(F), 505A, 505E, or 527 of the Federal Food, Drug, and Cosmetic Act; and

"(BB) if the application was submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act and references any listed drug, the last applicable date determined under subparagraph (A), (B), or (C) of section 505(c)(3) of such Act, or, if the application was submitted under section 505(j) of such Act, the last applicable date determined under clause (i), (ii), or (iii) of section 505(j)(5)(B) of such Act.

"(II) EXCLUSIVITY.—Nothing in this subparagraph shall be construed to affect section 351(k)(7)(D) of the Public Health Service Act.

"(v) LISTING.—The Secretary may continue to review an application after March 23, 2020, pursuant to clause (i), and continue to identify any applicable listed drug pursuant to clause (ii) on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, even if such review or listing may reveal the existence of such application and the identity of any listed drug for which the investigations described in section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act are relied upon by the applicant for approval of the pending application. Nothing in this subparagraph shall be construed as authorizing the Secretary to disclose any other information that is a trade secret or confidential information described in section 552(b)(4) of title 5, United States Code.

"(vi) SUNSET.—Beginning on October 1, 2022, this subparagraph shall have no force or effect and any applications described in clause (i) that have not been approved shall be deemed withdrawn.".