116TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
116–48

PURPLE BOOK CONTINUITY ACT OF 2019

MAY 3, 2019.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 1520]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1520) to amend the Public Health Service Act to provide for the publication of a list of licensed biological products, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Purple Book Continuity Act of 2019".

SEC. 2. PUBLIC LISTING.

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

"(9) PUBLIC LISTING.—

"(A) IN GENERAL.—

"(i) INITIAL PUBLICATION.—Not later than 180 days after the date of enactment of the Purple Book Continuity Act of 2019, the Secretary shall publish and make available to the public in a searchable, electronic format—

"(I) a list in alphabetical order of the nonproprietary or proper name of each biological product for which a biologics license under subsection (a) or this subsection is in effect, or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, as of such date of enactment;

"(II) the date of approval of the marketing application and the application number; and

"(III) the marketing or licensure status of the biological product for which a biologics license under subsection (a) or this subsection is in effect or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

"(ii) REVISIONS.—Every 30 days after the publication of the first list under clause (i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period.

"(iii) PATENT INFORMATION.—Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (l)(3)(A) or (l)(7), the reference product sponsor shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.

"(iv) LISTING OF EXCLUSIVITIES.—For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period that is applicable and has not concluded under paragraph (6) or paragraph (7).

"(B) WITHDRAWAL OR SUSPENSION OF LICENSURE.—If the licensing of a biological product was withdrawn or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If the withdrawal or suspension occurred after its publication in such list, the reference product sponsor shall notify the Secretary that—

"(i) the biological product shall be immediately removed from such list—

"(I) for the same period as the withdrawal or suspension; or

"(II) if the biological product has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety, purity, or potency reasons; and

"(ii) a notice of the removal shall be published in the Federal Register.".

SEC. 3. REVIEW AND REPORT ON TYPES OF INFORMATION TO BE LISTED.

Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) solicit public comment regarding the type of information, if any, that should be added to or removed from the list required by paragraph (9) of section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as added by section 2; and

(2) transmit to Congress an evaluation of such comments, including any recommendations about the types of information that should be added to or removed from the list.

PURPOSE AND SUMMARY

H.R. 1520, the "Purple Book Continuity Act of 2019" was introduced on March 5, 2019, by Rep. Anna G. Eshoo (D–CA) and referred to the Committee on Energy and Commerce. H.R. 1520 amends the Public Health Service Act (PHS Act) to codify publication of approved biological products in the Purple Book in a searchable, electronic format, specify that the Purple Book should be published electronically on the website of the Food and Drug Administration (FDA) and updated routinely, list relevant patents and exclusivities for biological products, and direct the FDA to consider the types of patents that should be listed in the Purple Book.

BACKGROUND AND NEED FOR LEGISLATION

In September 2014, the FDA published the first edition of the "Purple Book." Similar to the "Orange Book," which lists patents and exclusivities for small molecule drug products, the "Purple Book" lists biological products, including biosimilar and interchangeable biological products, that have been licensed by FDA under the PHS Act. The current "Purple Book" also includes the date the biological product was licensed and whether FDA evaluated the product for reference product exclusivity under section 351(k)(7) of the PHS Act. Publication of this list is not a statutory requirement and is currently published as a static document.

Stakeholders, such as prescribers, pharmacists, and manufacturers, utilize the "Purple Book" as a reference for product information and for development purposes. Some stakeholders have recommended that the "Purple Book" be improved to make it more functional, including making such information available in a searchable, electronic format, as well as to provide information regarding relevant exclusivities and to have such information updated more routinely.

H.R. 1520 would codify publication of the "Purple Book," outline specific requirements for the information that should be included in such publication, and directs FDA to solicit feedback about what further information should be included in the "Purple Book."

COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 1520:

The Subcommittee on Health held a legislative hearing entitled "Lowing the Cost of Prescription Drugs: Reducing Barriers to Market Competition" on March 13, 2019. The hearing considered H.R. 1520, the "Purple Book Continuity Act of 2019", and six other bills. The Subcommittee received testimony from the following witnesses:

- Lou Kennedy, Chief Executive Officer and Owner, Nephron Pharmaceuticals;
- Anthony Barrueta, Senior Vice President for Government Relations, Kaiser Permanente;

• Michael Carrier, Distinguished Professor, Rutgers Law School;
• Kurt Karst, Director, Hyman, Phelps & McNamara, P.C.;
• Jeff Kushan, Partner, Sidley Austin LLP;
• Marc M. Boutin, JD, Chief Executive Officer, National Health Council; and
• Chester "Chip" Davis, Jr., President and Chief Executive Officer, Association for Accessible Medicines.

COMMITTEE CONSIDERATION

H.R. 1520, the "Purple Book Continuity Act of 2019", was introduced on March 5, 2019, by Rep. Eshoo (D–CA), and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health on March 6, 2019. Following legislative hearings, the Subcommittee met in open markup session on H.R. 1520, pursuant to notice, on March 27, 2019, for consideration of the bill. A manager's amendment offered by Ms. Eshoo was adopted by a voice vote. Subsequently, the Subcommittee on Health agreed to a motion by Ms. Eshoo, Chairwoman of the Subcommittee, to favorably forward H.R. 1520 to the full Committee on Energy and Commerce, amended, by a voice vote.

The Committee on Energy and Commerce met in open markup session, pursuant to notice, on April 3, 2019, to consider H.R. 1520, as amended by the subcommittee. A bipartisan manager's amendment, offered by Ms. Eshoo and supported by Mr. Burgess, was adopted by a voice vote. At the conclusion of consideration and markup of the bill, the Committee agreed to a motion by Mr. Pallone, Chairman of the Committee, to order H.R. 1520 favorably reported to the House, amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 1520 during Committee markup. A motion by Mr. Pallone to order H.R. 1520 favorably reported to the House, amended, was agreed to by a voice vote.

OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of

the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

With respect to the requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the following cost estimate for H.R. 1520 from the Director of the Congressional Budget Office:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 3, 2019.

Hon. FRANK PALLONE, Jr.,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1520, the Purple Book Continuity Act of 2019.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Julia Christensen.

Sincerely,

KEITH HALL,
Director.

Enclosure.

H.R. 1520, Purple Book Continuity Act of 2019
As ordered reported by the House Committee on Energy and Commerce on April 3, 2019

Millions of Dollars	2019	2019-2024	2019-2029
Direct Spending (Outlays)	0	0	0
Revenues	0	0	0
Deficit Effect	0	0	0
Spending Subject to Appropriation (Outlays)	0	3	n.e.

Pay-as-you-go procedures apply?	No	Mandate Effects	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2030?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	Yes, Under Threshold

n.e. = not estimated.

Under current law, the Food and Drug Administration (FDA) publishes a reference guide for biological products, *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, commonly known as the "Purple Book." H.R. 1520 would codify publication of the Purple Book by FDA, require that the agency include more detailed information in the compendium, make the data available in a searchable electronic format, and update it every 30 days.

The Purple Book currently specifies whether a biological product licensed and marketed under section 351(k) of the Public Health Service Act (PHS) has been determined by FDA to be biosimilar to (or interchangeable with) the reference biological product. The Pur-

ple Book also includes the date a biological product was licensed for marketing under 351(a) of the PHS Act and whether FDA evaluated the biological product for reference product exclusivity. Information contained in the Purple Book is useful to health care practitioners and developers of biosimilar or interchangeable products and is updated periodically by FDA.

H.R. 1520 would require that the FDA proactively determine the reference product exclusivity for each licensed biological product listed in the Purple Book. The determination of reference product exclusivity is a complex, resource intensive assessment for the agency to make; thus, under current law it is generally made either for reasons of regulatory necessity or because the license holder that submitted the application requested the determination. The bill also would direct FDA to solicit public comments regarding the type of information that should be contained in the Purple Book and transmit a report to the Congress within three years after the date of enactment.

Based on the cost of similar activities, CBO expects that the FDA would require the equivalent of about 5 full-time employees in 2020 to cover the increased workload to comply with the listing and reporting requirements at cost of about $300,000 per employee. CBO expects that fewer employees would be needed in later years and that by 2023, ongoing personnel-related expenses to fulfill the bill's requirements would total less than $500,000 annually. CBO estimates that implementing the bill would cost FDA about $3 million over the 2020–2024 period. Such spending would be subject to the availability of appropriated funds.

H.R. 1520 would impose a private-sector mandate as defined in the Unfunded Mandates Reform Act (UMRA) by requiring biological product manufacturers to provide the FDA with certain patent information when that information is shared with biosimilar product manufacturers. CBO estimates the cost of the mandate would fall well below the private-sector threshold established in UMRA ($164 million in 2019, adjusted annually for inflation).

The CBO staff contacts for this estimate are Julia Christensen (for federal costs) and Andrew Laughlin (for mandates). The estimate was reviewed by Leo Lex, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to amend the PHS Act to provide for the publication of a list of licensed biological products and the patents and exclusivities related to such products, and to direct FDA to solicit public comment regarding the types of information that should be added or removed from the "Purple Book" and to transmit to Congress an evaluation of such comments.

DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 1520 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 1520 contains no earmarks, limited tax benefits, or limited tariff benefits.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that this Act may be cited as the "Purple Book Continuity Act of 2019".

Section 2. Public listing

Section 2 amends Section 351(k) of the PHS Act (42 U.S.C. 262(k)) to require the FDA to publish electronically within 180 days of enactment: a list of the nonproprietary or proper name of each biological product for which a biologics license is in effect or that has been deemed to be licensed; the date of approval of the marketing application and the application number; and the marketing or licensure status of the biological product for which a biologics license is in effect or that has been deemed to be licensed.

This section also requires the Secretary of Health and Human Services (the Secretary) to update the list every 30 days to include each new biological product that has been licensed during the previous 30-day period. The Secretary is required to include patent information provided by the reference product sponsor on the list no later than 30 days after a list of patents under subsection (l)(3)(A) of the PHS Act is provided to the subsection (k) applicant respecting a biological product on the list. In addition, the Secretary shall include on the list any applicable exclusivity periods for each biological product that has not concluded.

This section also specifies that any biological product that has had its licensing withdrawn or suspended for safety, purity, or potency reasons must be removed from the book. If the withdrawal or suspension of the license occurred after publication in the list, the reference product sponsor is required to notify the Secretary that: the biological product shall be immediately removed from the list for the same period as the withdrawal or suspension, or withdrawal of sale period; and a notice of removal will be published in the Federal Register.

Section 3. Review and report on types of biological products patents to be listed

Section 3 requires the Secretary to solicit public comment regarding the types of information that should be included in or removed from the list no later than 3 years after the date of enactment of this Act and requires an evaluation of such comments and any recommendations be transmitted to Congress.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS

SEC. 351. (a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required

under section 505B of the Federal Food, Drug, and Cosmetic Act.

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act.

(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

(ii) In this subparagraph, the terms "qualified indication" and "qualified data summary" have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d)(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5, United States Code.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this paragraph, the term "base quarter", as used with respect to a year, means the calendar

quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act (U.S.C., 1940 edition, title 21, ch. 9).

(h) A partially processed biological product which—

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this Act or the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et. seq.) if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biologi-

cal product is evaluated in an application submitted under subsection (k).

(j) The Federal Food, Drug, and Cosmetic Act, including the requirements under sections 505(o), 505(p), and 505–1 of such Act, applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

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

(2) CONTENT.—

(A) IN GENERAL.—

(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an

element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) GENERAL RULES.—

(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review

and approval of the application under which the reference product is licensed.

(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) GUIDANCE DOCUMENTS.—

(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) PUBLIC COMMENT.—

(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) CERTAIN PRODUCT CLASSES.—

(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product 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.

(9) PUBLIC LISTING.—

(A) IN GENERAL.—

(i) INITIAL PUBLICATION.—Not later than 180 days after the date of enactment of the Purple Book Continuity Act of 2019, the Secretary shall publish and make available to the public in a searchable, electronic format—

(I) a list in alphabetical order of the nonproprietary or proper name of each biological product for which a biologics license under subsection (a) or this subsection is in effect, or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, as of such date of enactment;

(II) the date of approval of the marketing application and the application number; and

(III) the marketing or licensure status of the biological product for which a biologics license under subsection (a) or this subsection is in effect or that has been deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(ii) REVISIONS.—Every 30 days after the publication of the first list under clause (i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period.

(iii) PATENT INFORMATION.—Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (l)(3)(A) or (l)(7), the reference product sponsor shall update the information provided to the Secretary under this clause with any

additional patents from such subsequent or supplemental list and their corresponding expiry dates.

(iv) LISTING OF EXCLUSIVITIES.—For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period that is applicable and has not concluded under paragraph (6) or paragraph (7).

(B) WITHDRAWAL OR SUSPENSION OF LICENSURE.—If the licensing of a biological product was withdrawn or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If the withdrawal or suspension occurred after its publication in such list, the reference product sponsor shall notify the Secretary that—

(i) the biological product shall be immediately removed from such list—

(I) for the same period as the withdrawal or suspension; or

(II) if the biological product has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety, purity, or potency reasons; and

(ii) a notice of the removal shall be published in the Federal Register.

(l) PATENTS.—

(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) IN GENERAL.—

(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

(I) OUTSIDE COUNSEL.—One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or infor-

mally, in patent prosecution relevant or related to the reference product.

(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) LIMITATION ON DISCLOSURE.—No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) USE OF CONFIDENTIAL INFORMATION.—Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) OWNERSHIP OF CONFIDENTIAL INFORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product

sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) EFFECT OF VIOLATION.—The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) SUBSECTION (k) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) LIST AND DESCRIPTION OF PATENTS.—

(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) LIST AND DESCRIPTION BY SUBSECTION (k) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) PATENT RESOLUTION NEGOTIATIONS.—

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

(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) PATENT RESOLUTION IF NO AGREEMENT.—

(A) NUMBER OF PATENTS.—The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) EXCHANGE OF PATENT LISTS.—

(i) IN GENERAL.—On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

(I) IN GENERAL.—Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) EXCEPTION.—If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

(A) ACTION IF AGREEMENT ON PATENT LIST.—If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

(i) NOTIFICATION TO SECRETARY.—Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

(A) NOTICE OF COMMERCIAL MARKETING.—The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) REASONABLE COOPERATION.—If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

(A) SUBSECTION (k) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (k) APPLICANT.—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) SUBSECTION (k) APPLICATION NOT PROVIDED.—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) PEDIATRIC STUDIES.—

(1) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (l), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

(2) MARKET EXCLUSIVITY FOR NEW BIOLOGICAL PRODUCTS.—If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such bio-

logical product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS.—If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7 years.

(4) EXCEPTION.—The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(4) is made later than 9 months prior to the expiration of such period.

(n) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

(1) IN GENERAL.—In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), references to the date of approval of such application, or licensure of the product subject to such application, shall mean the later of—

(A) the date an application is approved under subsection (a); or

(B) the date of issuance of the interim final rule controlling the biological product.

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