Union Calendar No.

116TH CONGRESS
1ST SESSION

H. R. 1520

[Report No. 116–]

To amend the Public Health Service Act to provide for the publication of a list of licensed biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2019

Ms. ESHOO introduced the following bill; which was referred to the Committee on Energy and Commerce

APRIL --, 2019

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on March 5, 2019]

A BILL

To amend the Public Health Service Act to provide for the publication of a list of licensed biological products, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

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.