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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

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.

IN THE HOUSE OF REPRESENTATIVES

March 5, 2019

M__. _____ introduced the following bill; which was referred to the Committee on _____

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 60 days after the date of enactment of the Purple Book Continuity Act of 2019, the Secretary shall publish and make available to the public electronically—

''(I) a list in alphabetical order of the official and proprietary name of each biological product for which a biologics license under subsection (a) or this subsection is in effect as of such date of enactment;

''(II) the date of licensing if the biological product is licensed after 1981 and the number of the application which was approved; and

''(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will

refer to the biological product published.

''(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.—When patent information 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 Secretary shall, in revisions made under clause (ii), include such information for such biological product.

''(B) DATE OF PUBLICATION.—A biological product for which a license is in effect under subsection (a) or this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the later of—

''(i) the date of its licensing; or

''(ii) the date of its publication in the list that—

''(I) was published under this section before the initial publication of the list under subparagraph (A); and

''(II) was equivalent to the list published under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act and comprised of patents associated with applications filed under subsection (a) of this section or under this subsection.

''(C) 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—

''(i) it shall be immediately removed from such list—

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

''(II) if the listed drug 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 BIOLOGICAL PRODUCT PATENTS 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) complete a review of, and formulate recommendations on, the types of biological product patents that should be included in 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) report such recommendations to the Congress.