

Union Calendar No. 26

116TH CONGRESS
1ST SESSION

H. R. 1520

[Report No. 116–48]

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

MAY 3, 2019

Additional sponsors: Mrs. CRAIG, Mrs. DINGELL, Mr. RUIZ, Mr. RUSH, Mr. PALLONE, Mr. KENNEDY, Mr. BURGESS, Ms. MATSUI, Ms. CLARKE of New York, Mr. VAN DREW, Mr. WALDEN, and Ms. MUCARSEL-POWELL

MAY 3, 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Purple Book Continuity*
5 *Act of 2019”.*

6 **SEC. 2. PUBLIC LISTING.**

7 *Section 351(k) of the Public Health Service Act (42*
8 *U.S.C. 262(k)) is amended by adding at the end the fol-*
9 *lowing:*

10 *“(9) PUBLIC LISTING.—*

11 *“(A) IN GENERAL.—*

12 *“(i) INITIAL PUBLICATION.—Not later*
13 *than 180 days after the date of enactment*
14 *of the Purple Book Continuity Act of 2019,*
15 *the Secretary shall publish and make avail-*
16 *able to the public in a searchable, electronic*
17 *format—*

18 *“(I) a list in alphabetical order of*
19 *the nonproprietary or proper name of*
20 *each biological product for which a bio-*
21 *logics license under subsection (a) or*
22 *this subsection is in effect, or that has*
23 *been deemed to be licensed under this*
24 *section pursuant to section 7002(e)(4)*
25 *of the Biologics Price Competition and*

1 *Innovation Act of 2009, as of such date*
2 *of enactment;*

3 “(II) *the date of approval of the*
4 *marketing application and the appli-*
5 *cation number; and*

6 “(III) *the marketing or licensure*
7 *status of the biological product for*
8 *which a biologics license under sub-*
9 *section (a) or this subsection is in ef-*
10 *fect or that has been deemed to be li-*
11 *censed under this section pursuant to*
12 *section 7002(e)(4) of the Biologics*
13 *Price Competition and Innovation Act*
14 *of 2009.*

15 “(ii) *REVISIONS.—Every 30 days after*
16 *the publication of the first list under clause*
17 *(i), the Secretary shall revise the list to in-*
18 *clude each biological product which has been*
19 *licensed under subsection (a) or this sub-*
20 *section during the 30-day period.*

21 “(iii) *PATENT INFORMATION.—Not*
22 *later than 30 days after a list of patents*
23 *under subsection (l)(3)(A), or a supplement*
24 *to such list under subsection (l)(7), has been*
25 *provided by the reference product sponsor to*

1 the subsection (k) applicant respecting a bi-
2 ological product included on the list pub-
3 lished under this subparagraph, the ref-
4 erence product sponsor shall provide such
5 list of patents (or supplement thereto) and
6 their corresponding expiry dates to the Sec-
7 retary, and the Secretary shall, in revisions
8 made under clause (ii), include such infor-
9 mation for such biological product. Within
10 30 days of providing any subsequent or
11 supplemental list of patents to any subse-
12 quent subsection (k) applicant under sub-
13 section (l)(3)(A) or (l)(7), the reference
14 product sponsor shall update the informa-
15 tion provided to the Secretary under this
16 clause with any additional patents from
17 such subsequent or supplemental list and
18 their corresponding expiry dates.

19 “(iv) LISTING OF EXCLUSIVITIES.—For
20 each biological product included on the list
21 published under this subparagraph, the Sec-
22 retary shall specify each exclusivity period
23 that is applicable and has not concluded
24 under paragraph (6) or paragraph (7).

1 “(B) *WITHDRAWAL OR SUSPENSION OF LI-*
2 *CENSURE.—If the licensing of a biological prod-*
3 *uct was withdrawn or suspended for safety, pu-*
4 *rity, or potency reasons, it may not be published*
5 *in the list under subparagraph (A). If the with-*
6 *drawal or suspension occurred after its publica-*
7 *tion in such list, the reference product sponsor*
8 *shall notify the Secretary that—*

9 “(i) *the biological product shall be im-*
10 *mediately removed from such list—*

11 “(I) *for the same period as the*
12 *withdrawal or suspension; or*

13 “(II) *if the biological product has*
14 *been withdrawn from sale, for the pe-*
15 *riod of withdrawal from sale or, if ear-*
16 *lier, the period ending on the date the*
17 *Secretary determines that the with-*
18 *drawal from sale is not for safety, pu-*
19 *rity, or potency reasons; and*

20 “(ii) *a notice of the removal shall be*
21 *published in the Federal Register.”.*

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

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

6 *(1) solicit public comment regarding the type of*
7 *information, if any, that should be added to or re-*
8 *moved from the list required by paragraph (9) of sec-*
9 *tion 351(k) of the Public Health Service Act (42*
10 *U.S.C. 262(k)), as added by section 2; and*

11 *(2) transmit to Congress an evaluation of such*
12 *comments, including any recommendations about the*
13 *types of information that should be added to or re-*
14 *moved from the list.*

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