

116TH CONGRESS
1ST SESSION

H. R. 1520

IN THE SENATE OF THE UNITED STATES

MAY 9, 2019

Received; read twice and referred to the Committee on Health, Education,
Labor, and Pensions

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Purple Book Con-
3 tinuity Act of 2019”.

4 **SEC. 2. PUBLIC LISTING.**

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

8 “(9) PUBLIC LISTING.—

9 “(A) IN GENERAL.—

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

16 “(I) a list in alphabetical order of
17 the nonproprietary or proper name of
18 each biological product for which a
19 biologics license under subsection (a)
20 or this subsection is in effect, or that
21 has been deemed to be licensed under
22 this section pursuant to section
23 7002(e)(4) of the Biologics Price
24 Competition and Innovation Act of
25 2009, as of such date of enactment;

1 “(II) the date of approval of the
2 marketing application and the applica-
3 tion number; and

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

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

19 “(iii) PATENT INFORMATION.—Not
20 later than 30 days after a list of patents
21 under subsection (l)(3)(A), or a supple-
22 ment to such list under subsection (l)(7),
23 has been provided by the reference product
24 sponsor to the subsection (k) applicant re-
25 specting a biological product included on

1 the list published under this subparagraph,
2 the reference product sponsor shall provide
3 such list of patents (or supplement there-
4 to) and their corresponding expiry dates to
5 the Secretary, and the Secretary shall, in
6 revisions made under clause (ii), include
7 such information for such biological prod-
8 uct. Within 30 days of providing any sub-
9 sequent or supplemental list of patents to
10 any subsequent subsection (k) applicant
11 under subsection (l)(3)(A) or (l)(7), the
12 reference product sponsor shall update the
13 information provided to the Secretary
14 under this clause with any additional pat-
15 ents from such subsequent or supplemental
16 list and their corresponding expiry dates.

17 “(iv) LISTING OF EXCLUSIVITIES.—
18 For each biological product included on the
19 list published under this subparagraph, the
20 Secretary shall specify each exclusivity pe-
21 riod that is applicable and has not con-
22 cluded under paragraph (6) or paragraph
23 (7).

24 “(B) WITHDRAWAL OR SUSPENSION OF LI-
25 CENSURE.—If the licensing of a biological prod-

1 uct was withdrawn or suspended for safety, pu-
2 rity, or potency reasons, it may not be pub-
3 lished in the list under subparagraph (A). If the
4 withdrawal or suspension occurred after its
5 publication in such list, the reference product
6 sponsor shall notify the Secretary that—

7 “(i) the biological product shall be im-
8 mediately removed from such list—

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

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

18 “(ii) a notice of the removal shall be
19 published in the Federal Register.”.

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

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

Attest: **CHERYL L. JOHNSON,**
Clerk.