

2125

1 “(2) includes any recommendations of the Sec-
2 retary for modifying the program under this sec-
3 tion.”.

4 **SEC. 325. BIOLOGICAL PRODUCT PATENT TRANSPARENCY.**

5 (a) IN GENERAL.—Section 351(k) of the Public
6 Health Service Act (42 U.S.C. 262(k)) is amended by add-
7 ing at the end the following:

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 this paragraph, the Secretary shall pub-
13 lish and make available to the public in a
14 searchable, electronic format—

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

2126

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

4 “(III) with respect to each bio-
5 logical product described in subclause
6 (I), the licensure status, and, as avail-
7 able, the marketing status.

8 “(ii) REVISIONS.—Every 30 days
9 after the publication of the first list under
10 clause (i), the Secretary shall revise the list
11 to include each biological product which
12 has been licensed under subsection (a) or
13 this subsection during the 30-day period or
14 deemed licensed under this section pursu-
15 ant to section 7002(e)(4) of the Biologics
16 Price Competition and Innovation Act of
17 2009.

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

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

16 “(iv) LISTING OF EXCLUSIVITIES.—
17 For each biological product included on the
18 list published under this subparagraph, the
19 Secretary shall specify each exclusivity pe-
20 riod under paragraph (6) or paragraph (7)
21 for which the Secretary has determined
22 such biological product to be eligible and
23 that has not concluded.

24 “(B) REVOCATION OR SUSPENSION OF LI-
25 CENSE.—If the license of a biological product is

1 determined by the Secretary to have been re-
2 voked or suspended for safety, purity, or po-
3 tency reasons, it may not be published in the
4 list under subparagraph (A). If such revocation
5 or suspension occurred after inclusion of such
6 biological product in the list published under
7 subparagraph (A), the reference product spon-
8 sor shall notify the Secretary that—

9 “(i) the biological product shall be im-
10 mediately removed from such list for the
11 same period as the revocation or suspen-
12 sion; and

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

15 (b) REVIEW AND REPORT ON TYPES OF INFORMA-
16 TION TO BE LISTED.—Not later than 3 years after the
17 date of enactment of this Act, the Secretary of Health and
18 Human Services shall—

19 (1) solicit public comment regarding the type of
20 information, if any, that should be added to or re-
21 moved from the list required by paragraph (9) of
22 section 351(k) of the Public Health Service Act (42
23 U.S.C. 262(k)), as added by subsection (a); and

24 (2) transmit to Congress an evaluation of such
25 comments, including any recommendations about the

1 types of information that should be added to or re-
2 moved from the list.

3 **Subtitle D—Technical Corrections**

4 **SEC. 331. TECHNICAL CORRECTIONS.**

5 (a) EDUCATION AND TRAINING RELATING TO GERI-
6 ATRICS.—Section 753(a)(7)(B) of the Public Health Serv-
7 ice Act (42 U.S.C. 294c(a)(7)(B)) is amended, in the mat-
8 ter preceding clause (i), by striking “Title VII Health
9 Care Workforce Reauthorization Act of 2019” and insert-
10 ing “Coronavirus Aid, Relief, and Economic Security
11 Act”.

12 (b) NURSING.—Section 851(d)(3) of the Public
13 Health Service Act (42 U.S.C. 297t(d)(3)) is amended by
14 striking “Title VIII Nursing Reauthorization Act” and in-
15 serting “Coronavirus Aid, Relief, and Economic Security
16 Act”.

17 (c) CITATION.—Section 3404(a)(9) of the
18 Coronavirus Aid, Relief, and Economic Security Act (Pub-
19 lic Law 116–136) is amended by striking “section 846A
20 (42 U.S.C. 247n–1)” and inserting “section 846A (42
21 U.S.C. 297n–1)”.

22 (d) EFFECTIVE DATE.—The amendments made by
23 subsections (a), (b), and (c) shall take effect as if included
24 in the enactment of the Coronavirus Aid, Relief, and Eco-
25 nomic Security Act (Public Law 116–136).