

119TH CONGRESS
2D SESSION

S. 4332

To require the Secretary of Health and Human Services to make determinations of the exclusivity periods for which licensed biological products are eligible.

IN THE SENATE OF THE UNITED STATES

APRIL 16 (legislative day, APRIL 14), 2026

Ms. HASSAN (for herself and Mr. BUDD) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To require the Secretary of Health and Human Services to make determinations of the exclusivity periods for which licensed biological products are eligible.

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 “Medication Competi-
5 tion Act”.

6 **SEC. 2. DETERMINATION OF REFERENCE PRODUCT EXCLU-**
7 **SIVITY.**

8 Section 351(k)(9)(A)(iv) of the Public Health Service
9 Act (42 U.S.C. 262(k)(9)(A)(iv)) is amended—

1 (1) by inserting “determine any applicable ex-
 2 clusivity period under paragraph (6) or (7), and
 3 shall” after “the Secretary shall”;

4 (2) by striking the period at the end and insert-
 5 ing “, as follows:”; and

6 (3) by adding at the end the following:

7 “(I) EXCLUSIVITY FOR FIRST
 8 INTERCHANGEABLE BIOLOGICAL
 9 PRODUCTS.—

10 “(aa) PRODUCTS LICENSED
 11 ON OR AFTER THE DATE OF EN-
 12 ACTMENT.—With respect to a bi-
 13 ological product licensed under
 14 this subsection on or after the
 15 date of enactment of the Medica-
 16 tion Competition Act, the Sec-
 17 retary shall include on the list
 18 published under this subpara-
 19 graph any applicable exclusivity
 20 period under paragraph (6), not
 21 later than 30 days after the ear-
 22 liest date on which an expiration
 23 date of such an exclusivity period
 24 can be known pursuant to para-
 25 graph (6).

1 “(bb) PRODUCTS LICENSED
2 BEFORE THE DATE OF ENACT-
3 MENT.—With respect to a bio-
4 logical product licensed under
5 this subsection before the date of
6 enactment of the Medication
7 Competition Act, the Secretary
8 shall include on the list published
9 under this subparagraph any ap-
10 plicable exclusivity period under
11 paragraph (6), not later than 30
12 days after the later of such date
13 of enactment or the earliest date
14 on which an expiration date of
15 such an exclusivity period can be
16 known pursuant to paragraph
17 (6).

18 “(II) EXCLUSIVITY FOR REF-
19ERENCE PRODUCTS.—

20 “(aa) PRODUCTS LICENSED
21 ON OR AFTER THE DATE OF EN-
22 ACTMENT.—With respect to a bi-
23 ological product licensed under
24 subsection (a) on or after the
25 date of enactment of the Medica-

tion Competition Act, the Secretary shall include on the list published under this subparagraph the expiration date of any exclusivity period under paragraph (7), not later than 30 days after licensure of the biological product.

“(bb) PRODUCTS LICENSED BEFORE THE DATE OF ENACTMENT.—With respect to any biological product licensed under subsection (a) before the date of enactment of the Medication Competition Act, the Secretary shall include on the list published under this subparagraph the expiration date of any exclusivity period under paragraph (7), not later than 2 years after such date of enactment.”.

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