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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. 7047

To amend title III of the Public Health Service Act with respect to the determination by the Secretary regarding certain biosimilar application elements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend title III of the Public Health Service Act with respect to the determination by the Secretary regarding certain biosimilar application elements, 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. DETERMINATION BY SECRETARY REGARDING**
4 **CERTAIN BIOSIMILAR APPLICATION ELE-**
5 **MENTS.**

6 Section 351(k)(2)(A)(ii) of the Public Health Service
7 Act (262(k)(2)(A)(ii)) is amended to read as follows:

1 “(ii) DETERMINATION BY SECRETARY
2 REGARDING CERTAIN APPLICATION ELE-
3 MENTS.—

4 “(I) IN GENERAL.—The Sec-
5 retary may determine, in the Sec-
6 retary’s discretion, that an element
7 described in clause (i)(I), or in clause
8 (i)(IV) with respect to the strength of
9 a biological product, is unnecessary in
10 an application submitted under this
11 subsection.

12 “(II) USE OF DETERMINATION.—
13 If the Secretary makes a determina-
14 tion under this clause that informa-
15 tion demonstrating that the strength
16 of the biological product is the same
17 as that of the reference product as de-
18 scribed in clause (i)(IV) is unneces-
19 sary, the term ‘reference product’
20 shall, for purposes of this section with
21 respect to such biological product, in-
22 clude all applicable strengths of the
23 reference product.”.