

117TH CONGRESS
1ST SESSION

S. 164

AN ACT

To educate health care providers and the public on biosimilar 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 “Advancing Education
3 on Biosimilars Act of 2021”.

4 **SEC. 2. EDUCATION ON BIOLOGICAL PRODUCTS.**

5 Subpart 1 of part F of title III of the Public Health
6 Service Act (42 U.S.C. 262 et seq.) is amended by adding
7 at the end the following:

8 **“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.**

9 “(a) INTERNET WEBSITE.—

10 “(1) IN GENERAL.—The Secretary may main-
11 tain and operate an internet website to provide edu-
12 cational materials for health care providers, patients,
13 and caregivers, regarding the meaning of the terms,
14 and the standards for review and licensing of, bio-
15 logical products, including biosimilar biological prod-
16 ucts and interchangeable biosimilar biological prod-
17 ucts.

18 “(2) CONTENT.—Educational materials pro-
19 vided under paragraph (1) may include—

20 “(A) explanations of key statutory and
21 regulatory terms, including ‘biosimilar’ and
22 ‘interchangeable’, and clarification regarding
23 the use of interchangeable biosimilar biological
24 products;

25 “(B) information related to development
26 programs for biological products, including bio-

1 similar biological products and interchangeable
2 biosimilar biological products and relevant clin-
3 ical considerations for prescribers, which may
4 include, as appropriate and applicable, informa-
5 tion related to the comparability of such biologi-
6 cal products;

7 “(C) an explanation of the process for re-
8 porting adverse events for biological products,
9 including biosimilar biological products and
10 interchangeable biosimilar biological products;
11 and

12 “(D) an explanation of the relationship be-
13 tween biosimilar biological products and inter-
14 changeable biosimilar biological products li-
15 censed under section 351(k) and reference
16 products (as defined in section 351(i)), includ-
17 ing the standards for review and licensing of
18 each such type of biological product.

19 “(3) FORMAT.—The educational materials pro-
20 vided under paragraph (1) may be—

21 “(A) in formats such as webinars, con-
22 tinuing education modules, videos, fact sheets,
23 infographics, stakeholder toolkits, or other for-
24 mats as appropriate and applicable; and

1 “(B) tailored for the unique needs of
2 health care providers, patients, caregivers, and
3 other audiences, as the Secretary determines
4 appropriate.

5 “(4) OTHER INFORMATION.—In addition to the
6 information described in paragraph (2), the Sec-
7 retary shall continue to publish—

8 “(A) the action package of each biological
9 product licensed under subsection (a) or (k) of
10 section 351; or

11 “(B) the summary review of each biological
12 product licensed under subsection (a) or (k) of
13 section 351.

14 “(5) CONFIDENTIAL AND TRADE SECRET IN-
15 FORMATION.—This subsection does not authorize
16 the disclosure of any trade secret, confidential com-
17 mercial or financial information, or other matter de-
18 scribed in section 552(b) of title 5.

19 “(b) CONTINUING EDUCATION.—The Secretary shall
20 advance education and awareness among health care pro-
21 viders regarding biological products, including biosimilar
22 biological products and interchangeable biosimilar biologi-
23 cal products, as appropriate, including by developing or
24 improving continuing education programs that advance
25 the education of such providers on the prescribing of, and

- 1 relevant clinical considerations with respect to, biological
- 2 products, including biosimilar biological products and
- 3 interchangeable biosimilar biological products.”.

Passed the Senate March 3, 2021.

Attest:

Secretary.

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