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 Representatives of the United States of America in Congress assembled,
SECTION 1. SHORT TITLE.

This Act may be cited as the “Advancing Education on Biosimilars Act of 2021”.

SEC. 2. EDUCATION ON BIOLOGICAL PRODUCTS.

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

“SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.

“(a) INTERNET WEBSITE.—

“(1) IN GENERAL.—The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

“(2) CONTENT.—Educational materials provided under paragraph (1) may include—

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

“(B) information related to development programs for biological products, including bio-
similar biological products and interchangeable
biosimilar biological products and relevant clin-
ical considerations for prescribers, which may
include, as appropriate and applicable, informa-
tion related to the comparability of such biologi-
cal products;

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

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

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

“(A) in formats such as webinars, con-
tinuing education modules, videos, fact sheets,
infographics, stakeholder toolkits, or other for-
mats as appropriate and applicable; and
“(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

“(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish—

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

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

“(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

“(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and
relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.”.

Passed the Senate March 3, 2021.

Attest:

Secretary.
To educate health care providers and the public on biosimilar biological products, and for other purposes.

AN ACT

S. 164