AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 4273 OFFERED BY MR. JOYCE OF PENNSYLVANIA

Insert after section 6 the following (and make such conforming changes as may be necessary):

SEC. 7. SUPPORTING ACCESSIBLE, FLEXIBLE, AND EFFECTIVE STANDARDS FOR SUNSCREEN ACTIVE INGREDIENTS.

(a) IN GENERAL.—Section 505G of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h) is amended by adding at the end the following:

''(r) REGULATIONS ESTABLISHING REQUIREMENTS FOR SUNSCREEN ACTIVE INGREDIENTS.—

''(1) EVIDENCE AND TESTING STANDARDS FOR SUNSCREEN ACTIVE INGREDIENTS.—The Secretary shall establish, through guidance or regulation, standards for evaluating the safety and efficacy of sunscreen active ingredients, provided that such standards—

''(A) ensure the safety of consumers based on a comprehensive evaluation of scientific evidence;

''(B) allow for the use of real-world evidence (as defined in section 505F(b)), observational studies, and other scientifically valid approaches in place of, or to supplement, traditional clinical tests to demonstrate safety and effectiveness; and

''(C) apply subsection (b)(6)(C) to the regulation of sunscreen active ingredients in demonstrating a prima facie safe nonprescription marketing and use.

''(2) NON-ANIMAL TESTING METHODS FOR SUNSCREEN ACTIVE INGREDIENTS.—

''(A) IN GENERAL.—The Secretary shall consider the types of nonclinical tests described in paragraphs (1) through (4) of the first subsection (z) of section 505 (as inserted by section 3209(a)(2) of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022 (division FF of Public Law 117–328)), or any other alternative to animal testing that the Secretary deems appropriate, in the consideration of sunscreen active ingredients.

''(B) GUIDANCE.—Not later than 180 days after the date of enactment of this subsection,

the Secretary shall issue new guidance on how sponsors can use nonclinical testing alternatives to animal testing to meet safety and efficacy standards for sunscreen active ingredients.''.

(b) SUNSCREEN FINAL ADMINISTRATIVE ORDER.—The final administrative order on pending over-the-counter sunscreen active ingredient submissions issued under section 3854 of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136; 21 U.S.C. 360fff–3 note) shall—

(1) account for historical data demonstrating safe use of sunscreen active ingredients that have previously been accepted for marketing in the United States;

(2) emphasize that sunscreen is an effective skin cancer prevention tool; and

(3) incorporate the evidence and testing standards for sunscreen active ingredients detailed in section 505G(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h) (as added by section 3).

(c) REPORTING AND TRANSPARENCY.—

(1) TO CONGRESS.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall, beginning not later than 1 year after the date of enactment of this section, an-

nually submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing—

(A) the status of implementation of evidence and testing standards for sunscreen active ingredients, including—

(i) any adjustments to evidence or testing standards made under section 505G(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h) (as added by subsection (a)); and

(ii) the number and types of sunscreen active ingredient applications reviewed using the standards under such section 505G(r); and

(B) the progress of the Food and Drug Administration in allowing nonclinical testing alternatives to animal testing for the consideration of sunscreen active ingredients.

(2) PUBLICATION.—Not later than 7 days after the date on which the Secretary submits a report under paragraph (1), the Secretary shall publish

such report on the website of the Food and Drug Administration.