

110TH CONGRESS
1ST SESSION

H. R. 3084

To require the Food and Drug Administration to establish a standard for broad-spectrum protection in sunscreen products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 18, 2007

Mrs. LOWEY introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To require the Food and Drug Administration to establish a standard for broad-spectrum protection in sunscreen 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Skin Cancer Preven-
5 tion, Education, and Consumer Right-To-Know Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) Skin cancer is a growing epidemic in the
9 United States with more than 1,000,000 new cases
10 diagnosed each year.

1 (2) About 10,000 Americans die each year from
2 skin cancer.

3 (3) The most deadly form of skin cancer, mela-
4 noma, has tripled among Caucasians since 1980.

5 (4) One in 5 Americans and one in 3 Cauca-
6 sians will develop skin cancer in the course of a life-
7 time.

8 (5) A person's risk for skin cancer doubles if he
9 or she has had 5 or more sunburns.

10 (6) More than 90 percent of all skin cancers are
11 caused by sun exposure, yet fewer than 33 percent
12 of adults, adolescents, and children routinely use sun
13 protection.

14 (7) Most skin cancer is caused by prolonged ex-
15 posure to the ultraviolet rays from the sun. This in-
16 visible radiation is classified as UVA radiation and
17 UVB radiation.

18 (8) UVB radiation is the chief cause of sunburn
19 and skin cancer.

20 (9) UVA radiation is more constant, year-
21 round, and penetrates the skin more deeply, causing
22 both premature aging and skin cancer.

23 (10) Current United States sunscreen stand-
24 ards set by the Food and Drug Administration

1 (FDA) require protection from UVB radiation but
2 not UVA radiation.

3 (11) The current United States sunscreen
4 standards provide a false sense of security to Ameri-
5 cans, since their sunscreen is protecting successfully
6 against sunburn, but not adequately against other
7 forms of skin damage, including skin cancers. Con-
8 sumers may wrongly believe that their sunscreen is
9 sufficiently protecting them and therefore stay in the
10 sun longer.

11 **SEC. 3. BROAD-SPECTRUM SUNSCREEN STANDARD.**

12 (a) IN GENERAL.—Chapter V of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
14 ed—

15 (1) in section 502, by adding at the end the fol-
16 lowing:

17 “(y) If it is a drug that is a sunscreen product and
18 its labeling is in violation of section 566 .”; and

19 (2) by inserting after section 565 the following:

20 **“SEC. 566. BROAD-SPECTRUM SUNSCREEN STANDARD.**

21 “(a) LABELING.—The labeling of a drug that is a
22 sunscreen product and fails to meet the standard adopted
23 under subsection (b)(1) shall not—

24 “(1) describe the product using the term
25 ‘broad-spectrum’ (or any variant of such term); or

1 “(2) include the symbol described in subsection
2 (b)(2).

3 “(b) STANDARD; SYMBOL.—The Secretary shall—

4 “(1) adopt a standard for broad-spectrum pro-
5 tection in sunscreen products in order to better pro-
6 tect Americans from skin cancer and premature
7 aging; and

8 “(2) adopt an easily recognized symbol for in-
9 clusion in the labeling of sunscreen products meeting
10 such standard.

11 “(c) MINIMUM REQUIREMENTS.—

12 “(1) MINIMUM REQUIREMENTS.—In estab-
13 lishing the standard under subsection (b)(1), the
14 Secretary shall require—

15 “(A) a minimum ratio 1 to 3 of UVA pro-
16 tection factor (UVA-PF) to sun protection fac-
17 tor (SPF);

18 “(B) a critical wavelength of 370
19 nanometers, as obtained in application of the
20 critical wavelength testing method;

21 “(C) a minimum level of UVB radiation
22 protection of sun protection factor 6 as ob-
23 tained in application of the International Sun
24 Protection Factor Test Methods (2006) or an

1 equivalent degree of protection obtained with
2 any in vitro method; and

3 “(D) truth in labeling requirements such
4 that—

5 “(i) claims of broad-spectrum protec-
6 tion from ultraviolet radiation can only be
7 made in cases where the product meets the
8 requirements established under this sec-
9 tion; and

10 “(ii) labels claiming broad-spectrum
11 protection include the symbol described in
12 subsection (b)(2) only if the sunscreen
13 product meets the standard adopted under
14 subsection (b)(1).

15 “(2) MEASUREMENT OF PROTECTION LEV-
16 ELS.—The protection factors described in paragraph
17 (1) shall be measured using standardized, reproduc-
18 ible testing methods that take photo-degradation
19 into account. In considering such methods, the Sec-
20 retary shall give preference to in vitro testing meth-
21 ods.

22 “(d) REGULATIONS.—Not later than December 31,
23 2007, the Secretary shall issue comprehensive final regula-
24 tions for carrying out this section with respect to sun-
25 screen products.

1 “(e) DEFINITIONS.—

2 “(1) BROAD-SPECTRUM PROTECTION.—The
3 term ‘broad-spectrum protection’ means protection
4 from both UVA radiation and UVB radiation.

5 “(2) SUN PROTECTION FACTOR.—The term
6 ‘sun protection factor’ is the ratio between the ultra-
7 violet dose required to produce minimal erythema re-
8 action (redness) in protected skin (skin with sun-
9 screen) compared to unprotected skin (skin without
10 any sunscreen). The number indicates how many
11 times longer a person can stay in the sun before be-
12 ginning to burn while wearing sun protection than if
13 he or she were not wearing any sunscreen at all.

14 “(3) UVA PROTECTION FACTOR.—The term
15 ‘UVA protection factor’ means the ratio of the min-
16 imum UVA radiation dose necessary to induce a per-
17 sistent pigment darkening on the skin protected by
18 a sunscreen product to the minimal UVA radiation
19 dose necessary to induce the minimal darkening ef-
20 fect on the same unprotected skin.

21 “(4) UVA RADIATION.—The term ‘UVA radi-
22 ation’ means sun radiation in the spectrum of 320
23 to 400 nanometers.

1 “(5) UVB RADIATION.—The term ‘UVB radi-
2 ation’ means sun radiation in the spectrum of 290
3 to 320 nanometers.”.

4 (b) EFFECTIVE DATE.—The requirements of sections
5 502(y) and 566(a) of the Federal Food, Drug, and Cos-
6 metic Act, as added by subsection (a), shall take effect
7 on the earlier of—

8 (1) the date determined appropriate by the Sec-
9 retary of Health and Human Services; or

10 (2) the date that is 1 year after the date of the
11 enactment of this Act.

12 **SEC. 4. EDUCATION.**

13 (a) EDUCATION.—Upon issuing the regulations re-
14 quired by subsection (d) of section 566 of the Federal
15 Food, Drug, and Cosmetic Act, as added by section 3, the
16 Secretary of Health and Human Services shall implement
17 a general, nationwide education campaign identifying the
18 risks posed by sun exposure without the use of a sunscreen
19 providing broad-spectrum protection.

20 (b) CONTENTS.—The education campaign under this
21 section shall be designed to increase the level of knowledge
22 and awareness among the general public of the causes of
23 skin cancer, the risks posed by unprotected sun exposure,
24 the respective roles of UVA radiation and UVB radiation
25 (as defined in such section 566) in the development of skin

1 cancer, the effective application of sunscreen, and the re-
2 lease of the standard requiring broad-spectrum protection
3 (as defined in such section 566) in sunscreen products.

4 (c) DURATION.—The education campaign under this
5 section shall be implemented for not less than one year.

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