

116TH CONGRESS
1ST SESSION

S. 1636

To amend the Federal Food, Drug, and Cosmetic Act with respect to the scope of new chemical exclusivity.

IN THE SENATE OF THE UNITED STATES

MAY 23 (legislative day, MAY 22), 2019

Mr. ROBERTS (for himself, Ms. SMITH, and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the scope of new chemical exclusivity.

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 “Ensuring Innovation
5 Act”.

6 **SEC. 2. NEW CHEMICAL EXCLUSIVITY SCOPE.**

7 Chapter V of the Federal Food, Drug, and Cosmetic
8 Act is amended—

9 (1) in section 505 (21 U.S.C. 355)—

10 (A) in subsection (c)(3)(E)—

1 (i) in clause (ii), by striking “active
2 ingredient (including any ester or salt of
3 the active ingredient)” and inserting “ac-
4 tive moiety (as defined by the Secretary in
5 section 314.3 of title 21, Code of Federal
6 Regulations (or any successor regula-
7 tions))”; and

8 (ii) in clause (iii), by striking “active
9 ingredient (including any ester or salt of
10 the active ingredient)” and inserting “ac-
11 tive moiety (as defined by the Secretary in
12 section 314.3 of title 21, Code of Federal
13 Regulations (or any successor regula-
14 tions))”;

15 (B) in subsection (j)(5)(F)—

16 (i) in clause (ii), by striking “active
17 ingredient (including any ester or salt of
18 the active ingredient)” and inserting “ac-
19 tive moiety (as defined by the Secretary in
20 section 314.3 of title 21, Code of Federal
21 Regulations (or any successor regula-
22 tions))”; and

23 (ii) in clause (iii), by striking “active
24 ingredient (including any ester or salt of
25 the active ingredient)” and inserting “ac-

1 tive moiety (as defined by the Secretary in
2 section 314.3 of title 21, Code of Federal
3 Regulations (or any successor regula-
4 tions))”;

5 (C) in subsection (l)(2)(A)(i), by striking
6 “active ingredient (including any ester or salt of
7 the active ingredient)” and inserting “active
8 moiety (as defined by the Secretary in section
9 314.3 of title 21, Code of Federal Regulations
10 (or any successor regulations))”;

11 (D) in subsection (s), in the matter pre-
12 ceding paragraph (1), by striking “active ingre-
13 dient (including any ester or salt of the active
14 ingredient)” and inserting “active moiety (as
15 defined by the Secretary in section 314.3 of
16 title 21, Code of Federal Regulations (or any
17 successor regulations))”; and

18 (E) in subsection (u)(1), in the matter pre-
19 ceding subparagraph (A)—

20 (i) by striking “active ingredient (in-
21 cluding any ester or salt of the active in-
22 gredient)” and inserting “active moiety (as
23 defined by the Secretary in section 314.3
24 of title 21, Code of Federal Regulations (or
25 any successor regulations))”; and

1 (ii) by striking “same active ingre-
2 dient” and inserting “same active moiety”;

3 (2) in section 512(c)(2)(F) (21 U.S.C.
4 360b(c)(2)(F))—

5 (A) in clause (i), by striking “active ingre-
6 dient (including any ester or salt of the active
7 ingredient)” and inserting “active moiety (as
8 defined by the Secretary in section 314.3 of
9 title 21, Code of Federal Regulations (or any
10 successor regulations))”;

11 (B) in clause (ii), by striking “active ingre-
12 dient (including any ester or salt of the active
13 ingredient)” and inserting “active moiety (as
14 defined by the Secretary in section 314.3 of
15 title 21, Code of Federal Regulations (or any
16 successor regulations))”; and

17 (C) in clause (v), by striking “active ingre-
18 dient (including any ester or salt of the active
19 ingredient)” and inserting “active moiety (as
20 defined by the Secretary in section 314.3 of
21 title 21, Code of Federal Regulations (or any
22 successor regulations))”;

23 (3) in section 524(a)(4)(C) (21 U.S.C.
24 360n(a)(4)(C)), by striking “active ingredient (in-
25 cluding any ester or salt of the active ingredient)”

1 and inserting “active moiety (as defined by the Sec-
2 retary in section 314.3 of title 21, Code of Federal
3 Regulations (or any successor regulations))”;

4 (4) in section 529(a)(4)(A)(ii), by striking “ac-
5 tive ingredient (including any ester or salt of the ac-
6 tive ingredient)” and inserting “active moiety (as de-
7 fined by the Secretary in section 314.3 of title 21,
8 Code of Federal Regulations (or any successor regu-
9 lations))”; and

10 (5) in section 565A(a)(4)(D) (21 U.S.C.
11 360bbb-4a(a)(4)(D)), by striking “active ingredient
12 (including any ester or salt of the active ingredient)”
13 and inserting “active moiety (as defined by the Sec-
14 retary in section 314.3 of title 21, Code of Federal
15 Regulations (or any successor regulations))”.

○