

## 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.
- 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)"

- and inserting "active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))";
- (4) in section 529(a)(4)(A)(ii), by striking "active ingredient (including any ester or salt of the active ingredient)" and inserting "active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))"; and
  - (5) in section 565A(a)(4)(D) (21 U.S.C. 360bbb-4a(a)(4)(D)), by striking "active ingredient (including any ester or salt of the active ingredient)" and inserting "active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))".

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