

116TH CONGRESS
1ST SESSION

H. R. 4955

To amend the Federal Food, Drug, and Cosmetic Act to clarify the meaning
of a new chemical entity.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 31, 2019

Mr. ENGEL (for himself, Mr. GUTHRIE, Mr. SCHRADER, and Mr. HUDSON)
introduced the following bill; which was referred to the Committee on En-
ergy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to
clarify the meaning of a new chemical entity.

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 “Protecting Access to
5 Safe and Effective Medicines Act of 2019”.

6 **SEC. 2. CLARIFYING THE MEANING OF NEW CHEMICAL EN-**
7 **TITY.**

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

10 (1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E)—

(i) in clause (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

(ii) in clause (iii), 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))”;

(B) in subsection (j)(5)(F)—

(i) in clause (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

(ii) in clause (iii), by striking “active ingredient (including any ester or salt of

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

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

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

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

21 (i) by striking “active ingredient (in-
22 cluding any ester or salt of the active in-
23 gredient)” and inserting “active moiety (as
24 defined by the Secretary in section 314.3

1 of title 21, Code of Federal Regulations (or
2 any successor regulations))”; and

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

5 (2) in section 512(c)(2)(F) (21 U.S.C.
6 360b(c)(2)(F))—

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

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

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

1 (3) in section 524(a)(4)(C) (21 U.S.C.
2 360n(a)(4)(C)), by striking “active ingredient (in-
3 cluding any ester or salt of the active ingredient)”
4 and inserting “active moiety (as defined by the Sec-
5 retary in section 314.3 of title 21, Code of Federal
6 Regulations (or any successor regulations))”;

7 (4) in section 529(a)(4)(A)(ii) (21 U.S.C.
8 360ff(a)(4)(A)(ii)), by striking “active ingredient
9 (including any ester or salt of the active ingredient)”
10 and inserting “active moiety (as defined by the Sec-
11 retary in section 314.3 of title 21, Code of Federal
12 Regulations (or any successor regulations))”; and

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

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