

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.

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## 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 Energy and Commerce

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## 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)—

1 (A) in subsection (c)(3)(E)—

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

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

16 (B) in subsection (j)(5)(F)—

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

24 (ii) in clause (iii), by striking “active  
25 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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