

116TH CONGRESS
2D SESSION

S. 1636

AN ACT

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,*

1 **SECTION 1. CLARIFYING THE MEANING OF NEW CHEMICAL**
2 **ENTITY.**

3 (a) IN GENERAL.—Chapter V of the Federal Food,
4 Drug, and Cosmetic Act is amended—

5 (1) in section 505 (21 U.S.C. 355)—

6 (A) in subsection (c)(3)(E), by striking
7 “active ingredient (including any ester or salt of
8 the active ingredient)” each place it appears
9 and inserting “active moiety (as defined by the
10 Secretary in section 314.3 of title 21, Code of
11 Federal Regulations (or any successor regula-
12 tions))”;

13 (B) in subsection (j)(5)(F), by striking
14 “active ingredient (including any ester or salt of
15 the active ingredient)” each place it appears
16 and inserting “active moiety (as defined by the
17 Secretary in section 314.3 of title 21, Code of
18 Federal Regulations (or any successor regula-
19 tions))”;

20 (C) in subsection (l)(2)(A)—

21 (i) by amending clause (i) to read as
22 follows:

23 “(i) not later than 30 days after the date
24 of approval of such applications—

25 “(I) for a drug, no active moiety (as
26 defined by the Secretary in section 314.3

of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

“(II) for a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; and”; and

(ii) in clause (ii), by inserting “or biological product” before the period;

(D) by amending subsection (s) to read as follows:

“(s) REFERRAL TO ADVISORY COMMITTEE.—The Secretary shall—

“(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the approval of such drug or biological if it is—

“(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

“(B) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; or

“(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.”; and

(E) in subsection (u)(1), in the matter preceding subparagraph (A)—

(i) 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) by striking “same active ingredient” and inserting “same active moiety”;

(2) in section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F)), by striking “active ingredient (including any ester or salt of the active ingredient)”

1 each place it appears and inserting “active moiety
2 (as defined by the Secretary in section 314.3 of title
3 21, Code of Federal Regulations (or any successor
4 regulations))”;

5 (3) in section 524(a)(4) (21 U.S.C.
6 360n(a)(4)), by amending subparagraph (C) to read
7 as follows:

8 “(C) is for—

9 “(i) a human drug, no active moiety
10 (as defined by the Secretary in section
11 314.3 of title 21, Code of Federal Regula-
12 tions (or any successor regulations)) of
13 which has been approved in any other ap-
14 plication under section 505(b)(1); or

15 “(ii) a biological product, no active in-
16 gredient of which has been approved in any
17 other application under section 351 of the
18 Public Health Service Act.”;

19 (4) in section 529(a)(4) (21 U.S.C. 21 U.S.C.
20 360ff(a)(4)), by striking subparagraphs (A) and (B)
21 and inserting the following:

22 “(A) is for a drug or biological product
23 that is for the prevention or treatment of a rare
24 pediatric disease;

25 “(B)(i) is for such a drug—

1 “(I) that contains no active moiety (as
 2 defined by the Secretary in section 314.3
 3 of title 21, Code of Federal Regulations (or
 4 any successor regulations)) that has been
 5 previously approved in any other applica-
 6 tion under subsection (b)(1), (b)(2), or (j)
 7 of section 505; and

8 “(II) that is the subject of an applica-
 9 tion submitted under section 505(b)(1); or
 10 “(ii) is for such a biological product—

11 “(I) that contains no active ingredient
 12 that has been previously approved in any
 13 other application under section 351(a) or
 14 351(k) of the Public Health Service Act;
 15 and

16 “(II) that is the subject of an applica-
 17 tion submitted under section 351(a) of the
 18 Public Health Service Act;” and

19 (5) in section 565A(a)(4) (21 U.S.C. 360bbb–
 20 4a(a)(4)), by amending subparagraph (D) to read as
 21 follows:

22 “(D) is for—

23 “(i) a human drug, no active moiety
 24 (as defined by the Secretary in section
 25 314.3 of title 21, Code of Federal Regula-

1 tions (or any successor regulations)) of
 2 which has been approved in any other ap-
 3 plication under section 505(b)(1); or

4 “(ii) a biological product, no active in-
 5 gredient of which has been approved in any
 6 other application under section 351 of the
 7 Public Health Service Act.”.

8 (b) TECHNICAL CORRECTIONS.—Chapter V of the
 9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
 10 et seq) is amended—

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

12 (A) in subsection (c)(3)(E), by repealing
 13 clause (i); and

14 (B) in subsection (j)(5)(F), by repealing
 15 clause (i); and

16 (2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C.
 17 355a(c)(1)(A)(i)(II)), by striking “(c)(3)(D)” and
 18 inserting “(c)(3)(E)”.

Passed the Senate December 14, 2020.

Attest:

Secretary.

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