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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. CLARIFYING THE MEANING OF NEW CHEMICAL ENTITY.

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

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears 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), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(C) in subsection (l)(2)(A)—

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

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

''(I) for 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

''(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)''

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

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

''(C) is for—

''(i) a human 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 section 505(b)(1); or

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

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

''(A) is for a drug or biological product that is for the prevention or treatment of a rare pediatric disease;

''(B)(i) is for such a drug—

''(I) that contains no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 505; and

''(II) that is the subject of an application submitted under section 505(b)(1); or

''(ii) is for such a biological product—

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

''(II) that is the subject of an application submitted under section 351(a) of the Public Health Service Act;''; and

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

''(D) is for—

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

tions (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

"(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.".

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

(1) in section 505 (21 U.S.C. 355)—

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

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

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

Passed the Senate December 14, 2020.

Attest:

Secretary.

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