

S 1636 -- Redline

Introduced to Engrossed -- Ensuring Innovation Act

Deletions ~~struck~~ · Insertions underlined

1636 ~~Introduced~~Engrossed in Senate ~~(IS)]~~(ES)] <DOC> 116th CONGRESS ~~1st~~2d Session S.

1636 AN ACT 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.~~

~~SHORTCLARIFYING TITLE.~~THE MEANING OF NEW CHEMICAL ENTITY.

~~This (a) In General.--Chapter V of the Federal Food, Drug, and Cosmetic Act may is be amended-- cited (1) as in the section~~ Ensuring Innovation (21 Act'' U.S.C.

SEC. 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))'';

2--(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))'';

NEW (C) CHEMICAL in EXCLUSIVITY subsection SCOPE. (l)(2)(A)-- (i) by amending clause (i) to read as follows:

Chapter `` (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 Food, Regulations Drug, (or and any Cosmetic successor Act regulations)) is of amended-- which (1) has been approved in section any 505 other (21 application U.S.C. under this section;

355)-- or (A) `` (II) in for subsection a (c)(3)(E)-- biological (i) product, in no clause active (ii), by striking ``active ingredient (including any ester or salt of the which active has ingredient)'' been and approved inserting in ``active any moiety other (as application defined under by the Secretary in section 314.3351 of title the 21, Public Code Health of Service Federal Act; Regulations (or any successor regulations))'';

and 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) and in (ii) subsection (j)(5)(F)-- (i) in clause (ii), by striking ``active ingredient (including any ester or salt of the active ingredient)'' and inserting ``active `` or moiety biological (as product'' defined before by the Secretary period; in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

and (D) (ii) in clause (iii), by striking amending ``active subsection ingredient (s) (including to any read ester as or follows: 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))'';

(C) `` (s) in Referral subsection to (l)(2)(A)(i), Advisory by Committee.-- The striking Secretary ``active shall-- ingredient `` (1) (including refer any a ester drug or salt biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the active approval ingredient)'' of and such inserting drug ``active 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))''; regulations)) of which has been approved in any other application under this section;

(D) or in `` (B) subsection a (s), biological in product, theno matter active preceding paragraph (1), by striking ``active ingredient (including any ester or salt of the which active has ingredient)'' been and approved inserting in ``active any moiety other (as application defined under by the Secretary in section 314.3351 of title the 21, Public Code Health of Service Federal Act; Regulations (or any successor regulations))'';

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.'';

~~360b(c)(2)(F))--360b(c)(2)(F)), (A) in clause (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))'';~~

~~(B)(3) 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 314.3524(a)(4) of (21 title U.S.C. 21, Code of Federal Regulations (or any successor regulations))'';~~

~~and 360n(a)(4)), (C) in clause (v), by striking amending ``active subparagraph ingredient (C) (including to any read ester as or follows: 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))'';~~

~~(2) ``C) is for-- ``i) a human drug, no active moiety (as defined by the Secretary in section 524(a)(4)(C) 314.3 (21 of U.S.C. title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1);~~

~~360n(a)(4)(C)), or by ``ii) striking a ``active biological ingredient product, (including no any active ester ingredient or salt of the which active has ingredient)'' been and approved inserting in ``active any moiety other (as application defined under by the Secretary in section 314.3351 of title the 21, Public Code Health of Service Federal Act.''; Regulations (or any successor regulations))'';~~

~~(4) in section 529(a)(4)(A)(ii), 529(a)(4) by (21 striking U.S.C. ``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 21 (5) in section 565A(a)(4)(D) (21 U.S.C.~~

~~360bbb-360ff(a)(4)), 4a(a)(4)(D)), by striking ``active subparagraphs ingredient (A) (including and any (B) ester or salt of the active ingredient)'' and inserting ``active moiety (as defined by the Secretary following: in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''.~~

~~<all> ``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 (i) 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 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.''.~~

~~(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.~~

~~116th CONGRESS 2d Session S.~~

~~1636~~

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