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AMENDMENT TO 3962

OFFERED BY MR. HASTINGS OF FLORIDA

At the end of part 1 of subtitle C of title V of division C, add the following:

SEC. 2574. DRUG PRICE COMPETITION.

(a) FIRST APPLICANT.—Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B)(iv)—

(A) in subclause (II), by striking item (bb) and inserting the following:

"(bb) FIRST APPLICANT.—As used in this subsection, the term 'first applicant' means—

"(AA) an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application

that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug; or

"(BB) an applicant for the drug not described in item (AA) that satisfies the requirements of subclause (III)."; and

(B) by adding at the end the following:

"(III) An applicant described in subclause (II)(bb)(BB) shall—

"(aa) submit and lawfully maintain a certification described in paragraph (2)(A)(vii)(IV) or a statement described in paragraph (2)(A)(viii) for each unexpired patent for which a first applicant described in item (AA) had submitted a certification described in paragraph (2)(A)(vii)(IV) on the first day on which a substantially complete application containing

such a certification was submitted;

"(bb) with regard to each such unexpired patent for which the applicant submitted a certification described in paragraph (2)(A)(vii)(IV), no action for patent infringement was brought against the applicant within the 45-day period specified in paragraph (5)(B)(iii), or if an action was brought within such time period, the applicant has obtained the decision of a court (including a district court) that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity, and including a settlement order or consent decree signed and entered by the court stating that the patent is invalid or not infringed); and

"(cc) but for the effective date of approval provisions in subparagraphs (B) and (F) and sections 505A and 527, be eligible to receive immediately effective approval at a time before any other applicant has begun commercial marketing."; and

(2) in subparagraph (D)—

(A) in clause (i)(IV), by striking "The first applicant" and inserting "The first applicant, as defined in subparagraph (B)(iv)(II)(bb)(AA),"; and

(B) in clause (iii), in the matter preceding subclause (I)—

(i) by striking "If all first applicants forfeit the 180-day exclusivity period under clause (ii)"; and

(ii) by inserting "If all first applicants, as defined in subparagraph (B)(iv)(II)(bb)(AA), forfeit the 180-day exclusivity period under clause (ii) at a time at which no applicant has begun commercial marketing".

(b) EFFECTIVE DATE AND TRANSITIONAL PROVISION.—

(1) EFFECTIVE DATE.—The amendments made by subsection (a) shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) to which the amendments made by section 1102(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Public Law 108–173) apply.

(2) TRANSITIONAL PROVISION.—An application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), to which the 180-day exclusivity period described in paragraph (5)(iv) of such section does not apply, and that contains a certification under paragraph (2)(A)(vii)(IV) of such Act, shall be regarded as a previous application containing such a certification within the meaning of section 505(j)(5)(B)(iv) of such Act (as in effect before the amendments made by Medicare Prescription Drug Improvement and Modernization Act of 2003 (Public Law 108–173)) if—

(A) no action for infringement of the patent that is the subject of such certification was

brought against the applicant within the 45-day period specified in section 505(j)(5)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iii)), or if an action was brought within such time period, the applicant has obtained the decision of a court (including a district court) that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity, and including a settlement order or consent decree signed and entered by the court stating that the patent is invalid or not infringed);

(B) the application is eligible to receive immediately effective approval, but for the effective date of approval provisions in sections 505(j)(5)(B) (as in effect before the amendment made by Public Law 108–173), 505(j)(5)(F), 505A, and 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(B), 355(j)(5)(F), 355a, 360cc); and

(C) no other applicant has begun commercial marketing.