

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:

1 **SEC. 2574. DRUG PRICE COMPETITION.**

2 (a) **FIRST APPLICANT.**—Section 505(j)(5) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(j)(5)) is amended—

5 (1) in subparagraph (B)(iv)—

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

8 “(bb) **FIRST APPLICANT.**—
9 As used in this subsection, the
10 term ‘first applicant’ means—

11 “(AA) an applicant
12 that, on the first day on
13 which a substantially complete application containing
14 a certification described in
15 paragraph (2)(A)(vii)(IV) is
16 submitted for approval of a
17 drug, submits a substan-
18 tially complete application
19

1 that contains and lawfully
2 maintains a certification de-
3 scribed in paragraph
4 (2)(A)(vii)(IV) for the drug;
5 or

6 “(BB) an applicant for
7 the drug not described in
8 item (AA) that satisfies the
9 requirements of subclause
10 (III).”; and

11 (B) by adding at the end the following:

12 “(III) An applicant described in
13 subclause (II)(bb)(BB) shall—

14 “(aa) submit and lawfully
15 maintain a certification described
16 in paragraph (2)(A)(vii)(IV) or a
17 statement described in paragraph
18 (2)(A)(viii) for each unexpired
19 patent for which a first applicant
20 described in item (AA) had sub-
21 mitted a certification described in
22 paragraph (2)(A)(vii)(IV) on the
23 first day on which a substantially
24 complete application containing

1 such a certification was sub-
2 mitted;
3 “(bb) with regard to each
4 such unexpired patent for which
5 the applicant submitted a certifi-
6 cation described in paragraph
7 (2)(A)(vii)(IV), no action for pat-
8 ent infringement was brought
9 against the applicant within the
10 45-day period specified in para-
11 graph (5)(B)(iii), or if an action
12 was brought within such time pe-
13 riod, the applicant has obtained
14 the decision of a court (including
15 a district court) that the patent
16 is invalid or not infringed (in-
17 cluding any substantive deter-
18 mination that there is no cause
19 of action for patent infringement
20 or invalidity, and including a set-
21 tlement order or consent decree
22 signed and entered by the court
23 stating that the patent is invalid
24 or not infringed); and

1 “(cc) but for the effective
2 date of approval provisions in
3 subparagraphs (B) and (F) and
4 sections 505A and 527, be eligi-
5 ble to receive immediately effec-
6 tive approval at a time before
7 any other applicant has begun
8 commercial marketing.”; and

9 (2) in subparagraph (D)—

10 (A) in clause (i)(IV), by striking “The first
11 applicant” and inserting “The first applicant,
12 as defined in subparagraph
13 (B)(iv)(II)(bb)(AA),”; and

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

16 (i) by striking “If all first applicants
17 forfeit the 180-day exclusivity period under
18 clause (ii)”; and

19 (ii) by inserting “If all first appli-
20 cants, as defined in subparagraph
21 (B)(iv)(II)(bb)(AA), forfeit the 180-day ex-
22 clusivity period under clause (ii) at a time
23 at which no applicant has begun commer-
24 cial marketing”.

1 (b) EFFECTIVE DATE AND TRANSITIONAL PROVI-
2 SION.—

3 (1) EFFECTIVE DATE.—The amendments made
4 by subsection (a) shall be effective only with respect
5 to an application filed under section 505(j) of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
7 355(j)) to which the amendments made by section
8 1102(a) of the Medicare Prescription Drug Improve-
9 ment and Modernization Act of 2003 (Public Law
10 108–173) apply.

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

24 (A) no action for infringement of the pat-
25 ent that is the subject of such certification was

1 brought against the applicant within the 45-day
2 period specified in section 505(j)(5)(B)(iii) of
3 the Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 355(j)(5)(B)(iii)), or if an action was
5 brought within such time period, the applicant
6 has obtained the decision of a court (including
7 a district court) that the patent is invalid or not
8 infringed (including any substantive determina-
9 tion that there is no cause of action for patent
10 infringement or invalidity, and including a set-
11 tlement order or consent decree signed and en-
12 tered by the court stating that the patent is in-
13 valid or not infringed);

14 (B) the application is eligible to receive im-
15 mediately effective approval, but for the effec-
16 tive date of approval provisions in sections
17 505(j)(5)(B) (as in effect before the amend-
18 ment made by Public Law 108-173),
19 505(j)(5)(F), 505A, and 527 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C.
21 355(j)(5)(B), 355(j)(5)(F), 355a, 360cc); and

22 (C) no other applicant has begun commer-
23 cial marketing.

