107TH CONGRESS
2D SESSION

S. 2818

To amend the Federal Food, Drug, and Cosmetic Act to ensure that there is competition in the pharmaceutical industry and increased access to affordable drugs.

IN THE SENATE OF THE UNITED STATES

JULY 29, 2002

Mr. GREGG introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure that there is competition in the pharmaceutical industry and increased access to affordable drugs.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Timely Review and Increased Access to Affordable Drugs Act''.

SEC. 2. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.

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

(1) in paragraph (2)(A)(vii)—

(A) by striking ''a certification, the opinion of the applicant and to the best of his knowledge,'' and inserting ''a certification that, in the opinion of and to the best knowledge of the applicant,''; and

(B) by inserting after ''each patent'' the following: ''published by the Secretary under subsection (c)(2) at least 1 day before the date on which the application is filed''; and

(2) in paragraph (5)—

(A) in subparagraph (B)(iii)—

(i) by inserting after ''of a patent'' the following: ''published by the Secretary under subsection (c)(2) at least 1 day before the date on which the application is filed'';

(ii) by striking ''paragraph (2)(B)(i)'' each place it appears and inserting ''(2)(B)''; and

(iii) by adding at the end the following: ''If, in connection with an application for approval of a drug under this subsection, the applicant provides an owner of a patent notice under paragraph (2)(B)

with respect to the patent, and the owner of the patent fails to bring a civil action against the applicant for infringement of the patent on or before the date that is 45 days after the date on which the notice is received, the owner of the patent shall be barred from bringing a civil action against the applicant with respect to the application.'';

(B) by redesignating subparagraphs (C) and (D) as subparagraphs (E) and (F), respectively; and

(C) by inserting after subparagraph (B) the following:

''(C) AVAILABILITY OF 30-MONTH PERIOD.—

''(i) IN GENERAL.—The 30-month period provided under subparagraph (B)(iii) shall be available only with respect to patents published by the Secretary under subsection (c)(2) at least 1 day before the date on which the application is filed.

''(ii) AMENDMENT OF APPLICATION.—If an application is amended to include a certification described in paragraph

(2)(A)(vii)(IV), the 30-month period provided under subparagraph (B)(iii) shall be available with respect to the patent concerning which the certification was made.

''(iii) SUBSEQUENT PATENTS.—

''(I) SEPARATE APPLICATION.—Any patent published by the Secretary under subsection (c)(2) subsequent to the filing date but before approval of an application under this paragraph shall be addressed in a subsequent application if the subsequent applicant makes a certification described in subparagraph (2)(A)(vii)(IV) with respect to the patent, in which case the 30-month period provided under subparagraph (B)(iii) shall be available to the subsequently published patent.

''(II) REFERENCING INFORMATION IN THE PREVIOUS APPLICATION.—If a subsequent application is filed, the Secretary shall permit the applicant, to the extent that the Secretary determines it to be appropriate,

to reference information submitted in the previous application.''.

(b) CONFORMING AMENDMENTS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by striking ''(j)(5)(D)(ii)'' each place it appears and inserting ''(j)(5)(F)(ii)'';

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by striking ''(j)(5)(D)'' each place it appears and inserting ''(j)(5)(F)''; and

(3) in subsections (e) and (l), by striking ''505(j)(5)(D)'' each place it appears and inserting ''505(j)(5)(F)''.

SEC. 3. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by section 2) is amended—

(1) in subparagraph (B)(iv), by striking subclause (II) and inserting the following:

''(II) the earlier of—

''(aa) the date of a final decision of a court in a civil action described in clause (iii) from

which no appeal has been or can be taken; or

''(bb) the date of a settlement order or consent decree signed by a Federal judge that enters a final judgment and includes a finding that the patent that is the subject of the certification is invalid or not otherwise infringed;''; and

(2) by inserting after subparagraph (C) the following:

''(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

''(i) IN GENERAL.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited if the applicant—

''(I) fails to market the drug within 30 days after the date on which the approval of the application for the drug is made effective under subparagraph (B)(iii);

''(II) fails to market the drug—

''(aa) within 30 days after the date of a final decision of a

court or the date of a settlement order or consent decree in a civil action described in subparagraph (B)(iii); or

''(bb) if the application has not been approved before the date of such a decision, within 30 days after the date of approval of the application;

''(III) withdraws the application;

''(IV) amends the application from a certification under paragraph (2)(A)(vii)(IV) to a certification under paragraph (2)(A)(vii)(III);

''(V) fails to get tentative approval of the application within 30 months after the date on which the application is filed, if the failure is not caused by a change in the requirements for tentative approval of the application imposed after the date on which the application is filed; or

''(VI) enters into an agreement with the owner of the patent—

"(aa) that is the subject of the certification under paragraph (2)(A)(vii)(IV); and

"(bb) that the Federal Trade Commission determines has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

"(ii) SUBSEQUENT APPLICANT.—If an applicant forfeits the 180-day exclusivity period under clause (i)—

"(I) a subsequent application containing a certification period described in paragraph (2)(A)(vii)(IV) shall become effective immediately on approval; and

"(II) the subsequent applicant shall not be eligible for a 180-day ex-

clusivity period under subparagraph (B)(iv).''.

SEC. 4. BIOEQUIVALENCE.

(a) IN GENERAL.—The amendments to part 320 of title 21, Code of Federal Regulations, promulgated by the Commissioner of Food and Drugs on July 17, 1991 (57 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect as an exercise of authorities under sections 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 355, 371).

(b) EFFECT.—Subsection (a) does not affect the authority of the Commissioner of Food and Drugs to amend part 320 of title 21, Code of Federal Regulations.

SEC. 5. OVER-THE-COUNTER DRUGS.

Section 503(b)(3) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(3)) is amended—

(1) by striking ''(3) The Secretary may by regulation remove drugs'' and inserting the following:

''(3) REMOVAL OF CERTAIN DRUGS FROM REQUIREMENTS OF PARAGRAPH (1).—

''(A) IN GENERAL.—The Secretary may by regulation remove a drug''; and

(2) by adding at the end the following:

''(B) MISBRANDING.—A drug that is removed from the requirements of paragraph (1)

under subparagraph (A) shall be deemed to be misbranded under paragraph (1) in a case in which any person introduces the drug into interstate commerce in accordance with the requirements of paragraph (1).''.

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