

110TH CONGRESS
1ST SESSION

S. 1088

To amend the Federal Food, Drug, and Cosmetic Act with respect to market exclusivity for certain drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 11, 2007

Ms. STABENOW (for herself and Mr. LOTT) 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 market exclusivity for certain drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Lower Prices Reduced
5 with Increased Competition and Efficient Development of
6 Drugs Act” or the “Lower PRICED Drugs Act”.

1 **SEC. 2. GENERIC DRUG USE CERTIFICATION.**

2 (a) IN GENERAL.—Section 505(j)(2)(A) of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(j)(2)(A)) is amended—

5 (1) in clause (vii), by striking “; and” and in-
6 serting a semicolon;

7 (2) in clause (viii), by striking the period and
8 inserting “; and”;

9 (3) by inserting after clause (viii) the following:

10 “(ix) if with respect to a listed drug product re-
11 ferred to in clause (i) that contains an antibiotic
12 drug and the antibiotic drug was the subject of any
13 application for marketing received by the Secretary
14 under section 507 (as in effect before the date of en-
15 actment of the Food and Drug Administration Mod-
16 ernization Act of 1997) before November 20, 1997,
17 the approved labeling includes a method of use
18 which, in the opinion of the applicant, is claimed by
19 any patent, a statement that—

20 “(I) identifies the relevant patent and the
21 approved use covered by the patent; and

22 “(II) the applicant is not seeking approval
23 of such use under this subsection.”; and

24 (4) in the last sentence, by striking “clauses (i)
25 through (viii)” and inserting “clauses (i) through
26 (ix)”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 this section shall apply to any abbreviated new drug appli-
3 cation under section 505(j) of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 355(j)) that is submitted
5 on, before, or after the date of enactment of this Act.

6 **SEC. 3. PREVENTING ABUSE OF THE THIRTY-MONTH STAY-**
7 **OF-EFFECTIVENESS PERIOD.**

8 (a) IN GENERAL.—Section 505(j)(5)(B)(iii) of the
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 355(j)(5)(B)(iii)) is amended—

11 (1) in the second sentence by striking “may
12 order” and inserting “shall order”; and

13 (2) by adding at the end the following: “In de-
14 termining whether to shorten the thirty-month pe-
15 riod under this clause, the court shall consider the
16 totality of the circumstances, including whether the
17 plaintiff sought to extend the discovery schedule, de-
18 layed producing discovery, or otherwise acted in a
19 dilatory manner, and the public interest.”.

20 (b) EFFECTIVE DATE.—The amendments made by
21 this section shall apply to any stay of effectiveness period
22 under section 505(j)(5)(B)(iii) of the Federal Food, Drug,
23 and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iii)) pending
24 or filed on or after the date of enactment of this Act.

1 **SEC. 4. ENSURING PROPER USE OF PEDIATRIC EXCLU-**
2 **SIVITY.**

3 (a) IN GENERAL.—Section 505A of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is
5 amended by striking subsections (b) and (c) and inserting
6 the following:

7 “(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

8 “(1) IN GENERAL.—With respect to a pending
9 application under section 505(b)(1), each of the pe-
10 riods of time under this chapter specified in para-
11 graph (2) that is applicable with respect to the drug
12 involved is deemed to be extended by the period of
13 time determined under subsection (d) if, prior to ap-
14 proval of such application—

15 “(A) the Secretary determines that infor-
16 mation relating to the use in the pediatric pop-
17 ulation of the drug may produce health benefits
18 in that population;

19 “(B) the Secretary makes a written re-
20 quest to the sponsor of the application for one
21 or more pediatric studies, which request shall
22 include a timeframe for completing such stud-
23 ies;

24 “(C) the sponsor agrees to the request;

25 “(D) such studies are completed within
26 any such timeframe and the reports thereof

1 submitted in accordance with subsection (e)(2)
2 or accepted in accordance with subsection
3 (e)(3); and

4 “(E) based on the results of such studies,
5 the Secretary approves labeling for the drug
6 that provides specific, therapeutically meaning-
7 ful information about the use of the drug in pe-
8 diatric patients.

9 “(2) PERIOD OF TIME TO BE EXTENDED.—For
10 purposes of paragraph (1), the periods of time under
11 this chapter that are specified in this paragraph
12 with respect to the drug involved are the following:

13 “(A) In section 505:

14 “(i) In each of subsections
15 (c)(3)(E)(ii) and (j)(5)(F)(ii):

16 “(I) The period of five years.

17 “(II) The period of four years,
18 the period of forty-eight months, and
19 the period of seven and one-half years.

20 “(ii) In each of clauses (iii) and (iv)
21 of subsection (c)(3)(E), and in each of
22 clauses (iii) and (iv) of subsection
23 (j)(5)(F), the period of three years.

1 “(B) In section 527(a), the period of seven
2 years, in the case of a drug designated under
3 section 526 for a rare disease or condition.

4 “(C) In section 505, under subsections
5 (c)(3) and (j)(5)(B), the period of time during
6 which the approval of an application may not be
7 made effective, in the case of a drug that—

8 “(i) is the subject of a qualifying list-
9 ed patent for which a certification has been
10 submitted under subsection (b)(2)(A)(ii) or
11 (j)(2)(A)(vii)(II) of such section and for
12 which pediatric studies were submitted
13 prior to the expiration of the patent (in-
14 cluding any patent extensions);

15 “(ii) is the subject of a qualifying list-
16 ed patent for which a certification has been
17 submitted under subsections (b)(2)(A)(iii)
18 or (j)(2)(A)(vii)(III) of such section; or

19 “(iii) is the subject of a qualifying
20 listed patent for which a certification has
21 been submitted under subsection
22 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of such
23 section, and with respect to which, in the
24 patent infringement litigation resulting
25 from the certification, the court determines

1 that the patent is valid and would be in-
2 fringed.

3 With respect to subparagraph (C), the extension of
4 time that applies under this subsection begins on the
5 day after the date of the expiration of the patent in-
6 volved (including any patent extension).

7 “(3) QUALIFYING LISTED PATENT.—With re-
8 spect to a study submitted pursuant to paragraph
9 (1), information on the patent must be filed with the
10 Secretary as required under subsection (b)(1) or
11 (c)(2) of section 505 as of the date on which the
12 study was submitted to the Secretary pursuant to
13 paragraph (1) in order to be considered a qualifying
14 listed patent for purposes of this subsection.

15 “(c) MARKET EXCLUSIVITY FOR ALREADY-MAR-
16 KETED DRUGS.—

17 “(1) IN GENERAL.—With respect to an ap-
18 proved application under section 505(b)(1), each of
19 the periods of time under this chapter specified in
20 paragraph (2) that is applicable with respect to the
21 drug involved is deemed to be extended by the period
22 of time determined under subsection (d) if—

23 “(A) the Secretary determines that infor-
24 mation relating to the use in the pediatric pop-

1 ulation of the drug may produce health benefits
2 in that population;

3 “(B) the Secretary makes a written re-
4 quest to the holder of such application for one
5 or more pediatric studies, which request shall
6 include a timeframe for completing such stud-
7 ies;

8 “(C) the holder agrees to the request;

9 “(D) such studies are completed within
10 any such timeframe and the reports thereof
11 submitted in accordance with subsection (e)(2)
12 or accepted in accordance with subsection
13 (e)(3); and

14 “(E) based on the results of such studies,
15 the Secretary approves labeling for the drug
16 that provides specific, therapeutically meaning-
17 ful information about the use of the drug in pe-
18 diatric patients.

19 “(2) PERIOD OF TIME TO BE EXTENDED.—For
20 purposes of paragraph (1), the periods of time under
21 this chapter that are specified in this paragraph are
22 the periods of time referred to in subsection (b)(2),
23 as applied to the drug referred to in paragraph (1).
24 With respect to periods of time referred to in sub-
25 section (b)(2)(C) as applied to such drug, the exten-

1 sion of time that applies under this subsection be-
2 gins on the day after the date of the expiration of
3 the patent involved (including any patent extension).

4 “(3) QUALIFYING LISTED PATENT.—With re-
5 spect to a study submitted pursuant to paragraph
6 (1), a patent concerning a drug is a qualifying listed
7 patent for purposes of this subsection if the patent
8 meets the condition described in subsection (b)(3),
9 as applied to the drug referred to in paragraph
10 (1).”.

11 (b) LENGTH OF EXTENSION PERIOD.—Section 505A
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 355a) is amended—

14 (1) by redesignating subsections (d) through
15 (n) as subsections (e) through (o), respectively; and

16 (2) by inserting after subsection (c) the fol-
17 lowing:

18 “(d) DETERMINATION OF EXTENSION PERIOD.—

19 “(1) IN GENERAL.—For purposes of sub-
20 sections (b) and (c), the extension period determined
21 under this subsection with respect to a drug is the
22 following, as applicable:

23 “(A) 3 months, if the sales revenue for the
24 same active moiety that is projected under

1 paragraph (3) for the base year is
2 \$1,000,000,000 or more.

3 “(B) 6 months, if the sales revenue for the
4 same active moiety that is projected under
5 paragraph (3) for the base year is less than
6 \$1,000,000,000.

7 “(2) BASE YEAR.—For purposes of this sub-
8 section, the base year for the same active moiety is
9 the preceding 12 months from the date which mar-
10 ket exclusivity under Federal law for the drug would
11 expire in the absence of an extension under sub-
12 section (b) or (c).

13 “(3) PROJECTION OF SALES REVENUE.—

14 “(A) IN GENERAL.—For purposes of para-
15 graph (1), the Secretary shall make an estimate
16 of the sales revenue for a drug for a base year
17 on the basis of the sales histories of an appro-
18 priate sample of drugs over the 20-year period
19 preceding the date of the enactment of the
20 Lower PRICED Drugs Act, including data on
21 the sales revenue of the drug that has been in-
22 cluded in reports by IMS Health.

23 “(B) TIMING OF PROJECTION.—An esti-
24 mate under subparagraph (A) for a drug shall
25 be a projection made in advance of the base

1 year for the drug. In the case of an extension
2 period under subsection (b), the projection may
3 not be made earlier than the expiration of the
4 2-year period beginning on the date on which
5 the drug is approved by the Secretary under
6 section 505, unless all market exclusivity under
7 Federal law for the drug will, in the absence of
8 an extension under subsection (b), expire before
9 the expiration of such period, in which case the
10 projection shall be determined not later than 3
11 months before the beginning of the base year.

12 “(C) IMS HEALTH.—The reference in sub-
13 paragraph (A)(ii) to IMS Health is a reference
14 to the corporation Intercontinental Marketing
15 Services, first established in 1954, whose activi-
16 ties include the conduct of syndicated market
17 research studies of the pharmaceutical industry
18 and the international monitoring of prescription
19 drug sales.

20 “(4) CRITERIA.—The Secretary shall by regula-
21 tion establish criteria for making projections under
22 paragraph (1).”.

23 (c) FINAL RULE FOR CRITERIA FOR PROJECTION OF
24 SALES REVENUE; EFFECTIVE DATE.—

1 (1) FINAL RULE.—With respect to criteria
2 under subsection (d)(4) of section 505A of the Fed-
3 eral Food, Drug, and Cosmetic Act, as added by
4 subsection (b) of this section, the Secretary of
5 Health and Human Services shall promulgate the
6 final rule not later than 180 days after the date of
7 enactment of this Act.

8 (2) EFFECTIVE DATE.—The amendments made
9 by this subsection take effect 180 days after the
10 date of enactment of this Act, without regard to
11 whether the final rule under paragraph (1) has been
12 promulgated, subject to subsection (e). The pre-
13 ceding sentence does not affect the requirement
14 under paragraph (1) for the Secretary to promulgate
15 a final rule, notwithstanding circumstances under
16 the preceding sentence in which such amendments
17 have taken effect in the absence of a final rule.

18 (d) CONFORMING AMENDMENTS; TECHNICAL COR-
19 RECTIONS.—Section 505A of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 355a), as amended by subsection
21 (b)(1), is amended—

22 (1) in subsection (e)(4)(C), by inserting “of the
23 Public Health Service Act” after “499(j)(9)(B)(i)”;

1 (2) in subsection (f), by striking “subsection
2 (c)(3)(D)” each place it appears and inserting “sub-
3 section (c)(3)(E)”;

4 (3) in each of subsections (f) and (g), by strik-
5 ing “subsection (d)” each place such term appears
6 and inserting “subsection (e)”; and

7 (4) in subsection (o), by striking “under sub-
8 section (a) or (c)” and inserting “under subsection
9 (b) or (c)”.

10 (e) EFFECTIVE DATE.—The amendments made by
11 this section shall apply to requests by the Secretary of
12 Health and Human Services for pediatric studies under
13 section 505A of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 355a) after the date of enactment of this
15 Act.

16 **SEC. 5. CITIZEN PETITIONS AND PETITIONS FOR STAY OF**
17 **AGENCY ACTION.**

18 Section 505 of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 355) is amended by adding at the end the
20 following:

21 “(o) CITIZENS PETITIONS AND PETITIONS FOR STAY
22 OF AGENCY ACTION.—With respect to a pending applica-
23 tion submitted under subsection (b)(2) or (j), if a petition
24 is submitted to the Secretary that seeks to have the Sec-
25 retary take, or refrain from taking, any form of action

1 relating to the approval of the application, including a
2 delay in the effective date of the application, the following
3 shall apply:

4 “(1) NO DELAY OF APPROVAL.—The Secretary
5 shall not delay approval of an application submitted
6 under subsection (b)(2) or (j) while a petition is re-
7 viewed and considered. Consideration of a petition
8 shall be separate and apart from the review and ap-
9 proval of an application submitted under either such
10 subsection.

11 “(2) TIMING OF FINAL AGENCY ACTION.—The
12 Secretary shall take final agency action with respect
13 to a petition within 180 days of submission of that
14 petition. The Secretary shall not extend such 180-
15 day review period, even with consent of the peti-
16 tioner, for any reason, including based upon the sub-
17 mission of comments relating to a petition or supple-
18 mental information supplied by the petitioner. If the
19 Secretary has not taken final agency action on a pe-
20 tition by the date that is 180 days after the date of
21 submission of the petition, such petition shall be
22 deemed to have been denied on such date.

23 “(3) VERIFICATION.—The Secretary shall not
24 accept for review a petition unless it is signed and
25 contains the following verification: ‘I certify that, to

1 my best knowledge and belief: (a) this petition in-
2 cludes all information and views upon which the pe-
3 tition relies; (b) this petition includes representative
4 data and/or information known to the petitioner
5 which are unfavorable to the petition; and (c) I have
6 taken reasonable steps to ensure that any represent-
7 ative data and/or information which are unfavorable
8 to the petition were disclosed to me. I further certify
9 that the information upon which I have based the
10 action requested herein first became known to the
11 party on whose behalf this petition is filed on or
12 about _____. I received or expect
13 to receive payments, including cash and other forms
14 of consideration, from the following persons or orga-
15 nizations to file this petition:
16 _____. I verify under penalty of
17 perjury that the foregoing is true and correct.’, with
18 the date of the filing of such petition being inserted
19 in the first blank space, and the appropriate names
20 of persons or organizations being inserted in the sec-
21 ond blank space.

22 “(4) EXTENSION OF PERIOD.—The thirty-
23 month period referred to in subsection
24 (j)(5)(D)(i)(IV) shall automatically be extended by
25 the amount of time that lapses from the date that

1 the Secretary receives a petition and the date of
2 final agency action on that petition, without regard
3 to whether the Secretary grants, in whole or in part,
4 or denies, in whole or in part, that petition.

5 “(5) EXHAUSTION OF ADMINISTRATIVE REM-
6 EDIES.—

7 “(A) FINAL AGENCY ACTION WITHIN 180
8 DAYS.—The Secretary shall be considered to
9 have take final agency action on a petition re-
10ferred to in this subsection if—

11 “(i) during the 180-day period re-
12ferred to in paragraph (2), the Secretary
13 makes a final decision within the meaning
14 of section 10.45(d) of title 21, Code of
15 Federal Regulations (or any successor reg-
16ulation); or

17 “(ii) such period expires without the
18 Secretary having made such a final deci-
19sion.

20 “(B) DISMISSAL OF CERTAIN CIVIL AC-
21TIONS.—If a civil action is filed with respect to
22 a petition referred to in this subsection before
23 final agency action, the court shall dismiss the
24 action for failure to exhaust administrative rem-
25 edies.

1 “(6) ANNUAL REPORT ON DELAYS IN APPROV-
2 ALS PER PETITION.—The Secretary shall annually
3 submit to Congress a report that specifies—

4 “(A) the number of applications under
5 subsections (b)(2) and (j) that were approved
6 during the preceding 12-month period;

7 “(B) the number of petitions described in
8 this subsection that were submitted during such
9 period;

10 “(C) the number of such applications
11 whose effective dates were delayed by such peti-
12 tions during such period; and

13 “(D) the number of days by which the ap-
14 plications were so delayed.

15 “(7) EXCEPTION.—This subsection does not
16 apply to a petition that is made by the sponsor of
17 the application under subsection (b)(2) or (j) and
18 that seeks only to have the Secretary take or refrain
19 from taking any form of action with respect to that
20 application.

21 “(8) DEFINITION.—For purposes of this sub-
22 section, the term ‘petition’ includes any request to
23 the Secretary, without regard to whether the request
24 is characterized as a petition.”.

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