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S. 2300

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

FEBRUARY 16, 2006

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

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A BILL

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

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 ''Lower Prices Reduced with Increased Competition and Efficient Development of Drugs Act'' or the ''Lower PRICED Drugs Act''.

SEC. 2. GENERIC DRUG USE CERTIFICATION.

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

(1) in clause (vii), by striking ''; and'' and inserting a semicolon;

(2) in clause (viii), by striking the period and inserting ''; and'';

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

''(ix) if with respect to a listed drug product referred to in clause (i) that contains an antibiotic drug and the antibiotic drug was the subject of any application for marketing received by the Secretary under section 507 (as in effect before the date of enactment of the Food and Drug Administration Modernization Act of 1997) before November 20, 1997, the approved labeling includes a method of use which, in the opinion of the applicant, is claimed by any patent, a statement that—

''(I) identifies the relevant patent and the approved use covered by the patent; and

''(II) the applicant is not seeking approval of such use under this subsection.''; and

(4) in the last sentence, by striking ''clauses (i) through (viii)'' and inserting ''clauses (i) through (ix)''.

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

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

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

(1) in the second sentence by striking ''may order'' and inserting ''shall order''; and

(2) by adding at the end the following: ''In determining whether to shorten the thirty-month period under this clause, the court shall consider the totality of the circumstances, including whether the plaintiff sought to extend the discovery schedule, delayed producing discovery, or otherwise acted in a dilatory manner, and the public interest.''.

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

SEC. 4. ENSURING PROPER USE OF PEDIATRIC EXCLUSIVITY.

(a) DRUG PRODUCT.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by striking ''drug'' each place it appears and inserting ''drug product''.

(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—Section 505A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(b)) is amended—

(1) in the matter preceding paragraph (1), by—

(A) striking ''health'' and inserting ''therapeutically meaningful'';

(B) striking ''and'' after ''(which shall include a timeframe for completing such studies),''; and

(C) inserting '', and based on the results of such studies the Secretary approves labeling for the new drug product that provides specific, therapeutically meaningful information about the use of the drug product in pediatric patients'' after ''in accordance with subsection (d)(3)'';

(2) in paragraph (1)(A)—

(A) in clause (i), by—

(i) striking ''the period'' and inserting ''any period''; and

(ii) inserting ''that is applicable to the drug product at the time of initial approval'' after ''in subsection (j)(5)(F)(ii) of such section''; and

(B) in clause (ii), by—

(i) striking ''the period'' and inserting ''any period''; and

(ii) inserting ''that is applicable to the drug product at the time of initial approval'' after ''of subsection (j)(5)(F) of such section''; and

(3) in paragraph (2)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''a listed patent'' and inserting ''a patent that was either listed when the pediatric study was submitted to the Food and Drug Administration or listed as a result of the approval by the Food and Drug Administration of new pediatric labeling that is claimed by the patent, and''; and

(ii) in clause (ii) by striking ''a listed patent'' and inserting ''a patent that was either listed when the pediatric study was submitted to the Food and Drug Adminis-

tration or listed as a result of the approval by the Food and Drug Administration of new pediatric labeling that is claimed by the patent, and''; and

(B) in subparagraph (B), by striking ''a listed patent'' and inserting ''a patent that was either listed when the pediatric study was submitted to the Food and Drug Administration or listed as a result of the approval by the Food and Drug Administration of new pediatric labeling that is claimed by the patent, and''.

(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—Section 505A(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(c)) is amended—

(1) in the matter preceding paragraph (1), by—

(A) striking ''health'' and inserting ''therapeutically meaningful'';

(B) striking ''and'' after ''the studies are completed within any such timeframe,''; and

(C) inserting '', and based on the results of such studies the Secretary approves labeling for the approved drug product that provides specific, therapeutically meaningful information about the use of the drug product in pediatric

patients'' after ''in accordance with subsection (d)(3)'';

(2) in paragraph (1)(A)—

(A) in clause (i)—

(i) by striking ''the period'' and inserting ''any period''; and

(ii) by inserting ''that is applicable to the drug product at the time of initial approval'' after ''in subsection (j)(5)(F)(ii) of such section''; and

(B) in clause (ii)—

(i) by striking ''the period'' and inserting ''any period''; and

(ii) by inserting ''that is applicable to the drug product at the time of initial approval'' after ''of subsection (j)(5)(F) of such section''; and

(3) in paragraph (2)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''a listed patent'' and inserting ''a patent that was either listed when the pediatric study was submitted to the Food and Drug Administration or listed as a result of the approval by the Food and Drug Administration of

new pediatric labeling that is claimed by the patent, and''; and

(ii) in clause (ii), by striking ''a listed patent'' and inserting ''a patent that was either listed when the pediatric study was submitted to the Food and Drug Administration or listed as a result of the approval by the Food and Drug Administration of new pediatric labeling that is claimed by the patent, and''; and

(B) in subparagraph (B), by striking ''a listed patent'' and by inserting ''a patent that was either listed when the pediatric study was submitted to the Food and Drug Administration or listed as a result of the approval by the Food and Drug Administration of new pediatric labeling that is claimed by the patent, and''.

(d) THREE-MONTH EXCLUSIVITY.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by—

(1) by striking ''six months'' each place it appears and inserting ''three months'';

(2) by striking ''six-month'' each place it appears and inserting ''three-month'';

(3) by striking ''6-month'' each place it appears and inserting ''three-month'';

(4) in subsection (b)(1)(A)(i), by striking ''four and one-half years, fifty-four months, and eight years, respectively'' and inserting ''four years and three months, fifty-one months, and seven years and nine months, respectively''; and

(5) in subsection (c)(1)(A)(i), by striking ''four and one-half years, fifty-four months, and eight years, respectively'' and inserting ''four years and three months, fifty-one months, and seven years and nine months, respectively''.

(e) DEFINITION.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by adding at the end the following:

''(o) DRUG PRODUCT.—

''(1) IN GENERAL.—For purposes of this section, the term 'drug product' has the same meaning given such term in section 314.3(b) of title 21, Code of Federal Regulations (or any successor regulation).

''(2) SEPARATE DRUG PRODUCTS.—For purposes of this section, each dosage form of a drug product shall constitute a different drug product.''.

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

(1) by striking ''subsection (c)(3)(D)'' each place it appears and inserting ''subsection (c)(3)(E)''; and

(2) in subsection (n), by striking ''under subsection (a) or (c)'' and inserting ''under subsection (b) or (c)''.

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

SEC. 5. CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

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

''(o) CITIZENS PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.—With respect to any petition that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of an applica-

tion submitted under subsection (b)(2) or (j), the following shall apply:

''(1) NO DELAY OF APPROVAL.—The Secretary shall not delay approval of an application submitted under subsection (b)(2) or (j) while a petition is reviewed and considered. Consideration of a petition shall be separate and apart from the review and approval of an application submitted under either such subsection.

''(2) TIMING OF FINAL AGENCY ACTION.—The Secretary shall take final agency action with respect to a petition within six months of receipt of that petition. The Secretary shall not extend such six-month review period, even with consent of the petitioner, for any reason, including based upon the submission of comments relating to a petition or supplemental information supplied by the petitioner. If the Secretary has not taken final agency action on a petition by the date that is six months after the date of receipt of the petition, such petition shall be deemed to have been denied on such date.

''(3) VERIFICATION.—The Secretary shall not accept for review a petition unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition in-

cludes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is filed on or about _____. I verify under penalty of perjury that the foregoing is true and correct.', with the date of the filing of such petition inserted in the blank space.

''(4) EXTENSION OF PERIOD.—The thirty-month period referred to in subsection (j)(5)(D)(i)(IV) shall automatically be extended by the amount of time that lapses from the date that the Secretary receives a petition and the date of final agency action on that petition, without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, that petition.''.

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