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109TH CONGRESS
2D SESSION

H. R. 6022

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

IN THE HOUSE OF REPRESENTATIVES

JULY 28, 2006

Mr. WAXMAN (for himself, Mr. PALLONE, and Ms. DELAURO) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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 the 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 apply to any abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 355(j)) that is submitted on, before, or after the date of the 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 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 the enactment of this Act.

SEC. 4. ENSURING PROPER USE OF PEDIATRIC EXCLUSIVITY.

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

amended by striking subsections (b) and (c) and inserting the following:

"(b) MARKET EXCLUSIVITY FOR NEW DRUGS.—

"(1) IN GENERAL.—With respect to a pending application under section 505(b)(1), each of the periods of time under this chapter specified in paragraph (2) that is applicable with respect to the drug involved is deemed to be extended by the period of time determined under subsection (d) if, prior to approval of such application—

"(A) the Secretary determines that information relating to the use in the pediatric population of the drug may produce health benefits in that population;

"(B) the Secretary makes a written request to the sponsor of the application for one or more pediatric studies, which request shall include a timeframe for completing such studies;

"(C) the sponsor agrees to the request;

"(D) such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (e)(2) or accepted in accordance with subsection (e)(3); and

''(E) based on the results of such studies, the Secretary approves labeling for the drug or drug product that provides specific, therapeutically meaningful information about the use of the drug in pediatric patients.

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

''(A) In section 505:

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

''(I) The period of five years.

''(II) The period of four years, the period of forty-eight months, and the period of seven and one-half years.

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

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

''(C) In section 505, under subsections (c)(3) and (j)(5)(B), the period of time during

which the approval of an application may not be made effective, in the case of a drug that—

''(i) is the subject of a qualifying listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of such section and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions);

''(ii) is the subject of a qualifying listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of such section; or

''(iii) is the subject of a qualifying listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of such section, and with respect to which, in the patent infringement litigation resulting from the certification, the court determines that the patent is valid and would be infringed.

With respect to subparagraph (C), the extension of time that applies under this subsection begins on the

day after the date of the expiration of the patent involved (including any patent extension).

''(3) QUALIFYING LISTED PATENT.—With respect to a study submitted pursuant to paragraph (1), a patent concerning a drug is a qualifying listed patent for purposes of this subsection if the patent meets the condition described in subparagraph (A), or the condition described in subparagraph (B), as follows:

''(A) Information on the patent had been filed with the Secretary as required under subsection (b)(1) or (c)(2) of section 505 as of the date on which the study was submitted to the Secretary pursuant to paragraph (1).

''(B) After such date, the patent became subject to the requirement under such subsection to file information on the patent as a result of the approval by the Secretary of a use of the drug in the pediatric population, which use—

''(i) is described in the approved labeling referred to in paragraph (1)(D); and

''(ii) is claimed by the patent.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—

''(1) IN GENERAL.—With respect to an approved application under section 505(b)(1), each of the periods of time under this chapter specified in paragraph (2) that is applicable with respect to the drug involved is deemed to be extended by the period of time determined under subsection (d) if—

''(A) the Secretary determines that information relating to the use in the pediatric population of the drug may produce health benefits in that population;

''(B) the Secretary makes a written request to the holder of such application for one or more pediatric studies, which request shall include a timeframe for completing such studies;

''(C) the holder agrees to the request;

''(D) such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (e)(2) or accepted in accordance with subsection (e)(3); and

''(E) based on the results of such studies, the Secretary approves labeling for the drug that provides specific, therapeutically meaning-

ful information about the use of the drug in pediatric patients.

''(2) PERIOD OF TIME TO BE EXTENDED.—For purposes of paragraph (1), the periods of time under this chapter that are specified in this paragraph are the periods of time referred to in subsection (b)(2), as applied to the drug referred to in paragraph (1). With respect to periods of time referred to in subsection (b)(2)(C) as applied to such drug, the extension of time that applies under this subsection begins on the day after the date of the expiration of the patent involved (including any patent extension).

''(3) QUALIFYING LISTED PATENT.—With respect to a study submitted pursuant to paragraph (1), a patent concerning a drug is a qualifying listed patent for purposes of this subsection if the patent meets one of the conditions described in subparagraph (A) or (B) of subsection (b)(3), as applied to the drug referred to in paragraph (1).''.

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

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

(2) by inserting after subsection (c) the following:

''(d) DETERMINATION OF EXTENSION PERIOD.—

''(1) IN GENERAL.—For purposes of subsections (b) and (c), the extension period determined under this subsection with respect to a drug is the following, as applicable:

''(A) One month, if the sales revenue for the drug that is projected under paragraph (3) for the base year is $1,000,000,000 or more.

''(B) Two months, if the sales revenue for the drug that is so projected is $500,000,000 or more but less than $1,000,000,000.

''(C) Three months, if the sales revenue for the drug that is so projected is less than $500,000,000.

''(2) BASE YEAR.—For purposes of this subsection, the base year for a drug is the calendar year during which market exclusivity under Federal law for the drug would expire in the absence of an extension under subsection (b) or (c).

''(3) PROJECTION OF SALES REVENUE.—

''(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall make an estimate of the sales revenue for a drug for a base year

on the basis of the sales histories of an appropriate sample of drugs over the 20-year period preceding the date of the enactment of the Lower PRICED Drugs Act, including data on the sales revenue of the drug that has been included in reports by IMS Health.

''(B) TIMING OF PROJECTION.—An estimate under subparagraph (A) for a drug shall be a projection made in advance of the base year for the drug. In the case of an extension period under subsection (b), the projection may not be made earlier than the expiration of the two-year period beginning on the date on which the drug is approved by the Secretary under section 505, unless all market exclusivity under Federal law for the drug will, in the absence of an extension under subsection (b), expire before the expiration of such period, in which case the projection shall be determined not later than three months before the beginning of the base year.

''(C) IMS HEALTH.—The reference in subparagraph (A)(ii) to IMS Health is a reference to the corporation Intercontinental Marketing Services, first established in 1954, whose activi-

ties include the conduct of syndicated market research studies of the pharmaceutical industry and the international monitoring of prescription drug sales.

''(4) CRITERIA.—The Secretary shall by regulation establish criteria for making projections under paragraph (1).''.

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

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

(2) EFFECTIVE DATE.—The amendments made by this subsection take effect 180 days after the date of the enactment of this Act, without regard to whether the final rule under paragraph (1) has been promulgated, subject to subsection (e). The preceding sentence does not affect the requirement under paragraph (1) for the Secretary to promulgate a final rule, notwithstanding circumstances under

the preceding sentence in which such amendments have taken effect in the absence of a final rule.

(d) CONFORMING AMENDMENTS; TECHNICAL CORRECTIONS.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a), as amended by subsection (b)(1) of this section, is amended—

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

(2) in each of subsections (f) and (g), by striking ''subsection (d)'' each place such term appears and inserting ''subsection (e)''; and

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

(e) EFFECTIVE DATE.—The amendments made by this section 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 the 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) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

"(1) IN GENERAL.—With respect to a pending application under subsection (b)(2) or (j), if a petition is submitted to the Secretary that seeks to have the Secretary take, or refrain from taking, any form of action relating to the approval of the application, including a delay in the effective date of the application, the following applies, subject to paragraph (5):

"(A)(i) In the case of an application under subsection (b)(2), the Secretary may not, subject to clause (iii), consider the petition if it is submitted later than 210 days prior to the date on which the approval of the application may first be made effective under subsection (c)(3), including subparagraphs (C) and (E) (as applicable), or 210 days prior to the expiration of any 30-month stay under such subparagraph (C) with respect to the application, whichever is later.

"(ii) In the case of an application under subsection (j), the Secretary may not, subject to clause (iii), consider the petition if it is submitted later than 210 days prior to the date on which the approval of the application may first

be made effective under paragraph (5) of such subsection, including subparagraphs (B)(iii) and (F) (as applicable), or 210 days prior to the expiration of any 30-month stay under such subparagraph (B)(iii) with respect to the application, whichever is later.

''(iii) The restriction established in clause (i) or (ii) (as the case may be) does not apply to the petition if the Secretary determines that the petitioner has shown good cause for the failure to submit the petition by the applicable date under such clause.

''(B)(i) The Secretary may not, on the basis of the petition, delay approval of the application unless the Secretary determines that a delay is necessary to protect the public health. Consideration of a petition shall be separate and apart from the review and approval of the application.

''(ii) With respect to a determination by the Secretary under clause (i) that a delay is necessary to protect the public health:

''(I) The Secretary shall publish on the Internet site of the Food and Drug Ad-

ministration a statement providing the reasons underlying the determination.

"(II) Not later than 10 days after making the determination, the Secretary shall provide notice to the sponsor of the application and an opportunity for a meeting with the Commissioner to discuss the determination.

"(C) The Secretary shall take final agency action on the petition not later than 180 days after the date on which the petition is submitted. The Secretary shall not extend such period, even with the consent of the petitioner, for any reason, including based upon the submission of comments relating to the petition or supplemental information supplied by the petitioner.

"(D) If the filing of the application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV), the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such begin-

ning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

''(E) The Secretary may not consider the petition for review unless it is signed and contains the following verification: 'I certify that, to my best knowledge and belief: (a) this petition includes 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 submitted on or about the following date: _____. I received or expect to receive payments, including cash and other forms of consideration, from the following persons or organizations to file this petition: _____. I verify under

penalty of perjury that the foregoing is true and correct.'.

''(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

''(A) FINAL AGENCY ACTION WITHIN 180 DAYS .—The Secretary shall be considered to have taken final agency action on a petition referred to in paragraph (1) if—

''(i) during the 180-day period referred to in subparagraph (C) of such paragraph, the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations; or

''(ii) such period expires without the Secretary having made such a final decision.

''(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed with respect to a petition referred to in paragraph (1) before final agency action within the meaning of subparagraph (A) has occurred, the court shall dismiss the action for failure to exhaust administrative remedies.

''(3) APPLICABILITY OF CERTAIN REGULATIONS.—The provisions of this section are in addition to the requirements for the submission of a petition to the Secretary that apply under section 10.30 or 10.35 of title 21, Code of Federal Regulations.

''(4) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

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

''(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period; and

''(C) the number of days by which the applications were so delayed.

''(5) EXCEPTIONS.—This subsection does not apply to—

''(A) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

''(B) a petition that is made by the sponsor of an application under subsection (b)(2) or

(j) and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

''(6) DEFINITION.—For purposes of this subsection, the term 'petition' includes any request to the Secretary, without regard to whether the request is characterized as a petition.''.

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