

104TH CONGRESS  
2D SESSION

# S. 2178

To amend the Federal Food, Drug, and Cosmetic Act to allow for additional deferred effective dates for approval of applications under the new drugs provisions, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

SEPTEMBER 30, 1996

Mrs. KASSEBAUM (for herself, Mr. KENNEDY, Mr. DODD, Mr. DEWINE, Ms. MIKULSKI, and Mr. SIMON) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to allow for additional deferred effective dates for approval of applications under the new drugs provisions, 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 “Better Pharma-  
5       ceuticals for Children Act”.

1 **SEC. 2. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.**

2 Chapter V of the Federal Food, Drug, and Cosmetic  
3 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
4 section 505 the following new section:

5 **“SEC. 505A. PEDIATRIC STUDIES OF DRUGS.**

6 “(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If,  
7 prior to approval of an application that is submitted under  
8 section 505(b)(1) the Secretary determines that informa-  
9 tion relating to the use of a drug in the pediatric popu-  
10 lation may produce health benefits in that population, the  
11 Secretary makes a written request for pediatric studies  
12 (which may include a time frame for completing such stud-  
13 ies), and such studies are completed within any such time  
14 frame and the reports thereof submitted in accordance  
15 with subsection (d)(2) or completed within any such time  
16 frame and the reports thereof are accepted in accordance  
17 with subsection (d)(3)—

18 “(1)(A) the period during which an application  
19 may not be submitted under subsections  
20 (e)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be  
21 five years and six months rather than five years, and  
22 the references in subsections (e)(3)(D)(ii) and  
23 (j)(4)(D)(ii) of section 505 to four years, to forty-  
24 eight months, and to seven and one-half years shall  
25 be deemed to be four and one-half years, fifty-four  
26 months, and eight years, respectively; or

1           “(B) the period of market exclusivity under  
2 subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii)  
3 and (iv) of section 505 shall be three years and six  
4 months rather than three years; and

5           “(2)(A) if the drug is the subject of—

6           “(i) a listed patent for which a certification  
7 has been submitted under section  
8 505(b)(2)(A)(ii) or (j)(2)(A)(vii)(II) and for  
9 which pediatric studies were submitted prior to  
10 the expiration of the patent (including any pat-  
11 ent extensions), or

12           “(ii) a listed patent for which a certifi-  
13 cation has been submitted under section  
14 505(b)(2)(A)(iii) or section  
15 505(j)(2)(A)(vii)(III),

16 the period during which an application may not be  
17 approved under section 505(c)(3) or section  
18 505(j)(4)(B) shall be extended by a period of six  
19 months after the date the patent expires (including  
20 any patent extensions); or

21           “(B) if the drug is the subject of a listed patent  
22 for which a certification has been submitted under  
23 section 505(b)(2)(A)(iv) or section  
24 505(j)(2)(A)(vii)(IV), and in the patent infringement  
25 litigation resulting from the certification the court

1 determines that the patent is valid and would be in-  
2 fringed, the period during which an application may  
3 not be approved under section 505(c)(3) or section  
4 505(j)(4)(B) shall be extended by a period of six  
5 months after the date the patent expires (including  
6 any patent extensions).

7 “(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR  
8 WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE  
9 BENEFICIAL.—Not later than 180 days after the date of  
10 enactment of this section, the Secretary, after consultation  
11 with experts in pediatric research (such as the American  
12 Academy of Pediatrics, the Pediatric Pharmacology Re-  
13 search Unit Network, and the United States Pharma-  
14 copoeia) shall develop and publish an initial list of ap-  
15 proved drugs for which additional pediatric information  
16 may produce health benefits in the pediatric population.  
17 The Secretary shall annually update the list.

18 “(c) MARKET EXCLUSIVITY FOR ALREADY-MAR-  
19 KETED DRUGS.—If the Secretary makes a written request  
20 for pediatric studies (which may include a time frame for  
21 completing such studies) concerning a drug identified in  
22 the list described in subsection (b) to the holder of an ap-  
23 proved application under section 505(b)(1) for the drug,  
24 the holder agrees to the request, and the studies are com-  
25 pleted within any such time frame and the reports thereof

1 submitted in accordance with subsection (d)(2) or com-  
2 pleted within any such time frame and the reports thereof  
3 accepted in accordance with subsection (d)(3)—

4 “(1)(A) the period during which an application  
5 may not be submitted under subsections  
6 (c)(3)(D)(ii) and (j)(4)(D)(ii) of section 505 shall be  
7 five years and six months rather than five years, and  
8 the references in subsections (c)(3)(D)(ii) and  
9 (j)(4)(D)(ii) of section 505 to four years, to forty-  
10 eight months, and to seven and one-half years shall  
11 be deemed to be four and one-half years, fifty-four  
12 months, and eight years, respectively; or

13 “(B) the period of market exclusivity under  
14 subsections (c)(3)(D) (iii) and (iv) and (j)(4)(D) (iii)  
15 and (iv) of section 505 shall be three years and six  
16 months rather than three years; and

17 “(2)(A) if the drug is the subject of (i) a listed  
18 patent for which a certification has been submitted  
19 under section 505(b)(2)(A)(ii) or (j)(2)(A)(vii)(II)  
20 and for which pediatric studies were submitted prior  
21 to the expiration of the patent (including any patent  
22 extensions), or (ii) a listed patent for which a certifi-  
23 cation has been submitted under section  
24 505(b)(2)(A)(iii) or section 505(j)(2)(A)(vii)(III),  
25 the period during which an application may not be

1 approved under section 505(c)(3) or section  
2 505(j)(4)(B) shall be extended by a period of six  
3 months after the date the patent expires (including  
4 any patent extensions); or

5 “(B) if the drug is the subject of a listed patent  
6 for which a certification has been submitted under  
7 section 505(b)(2)(A)(iv) or section  
8 505(j)(2)(A)(vii)(IV), and in the patent infringement  
9 litigation resulting from the certification the court  
10 determines that the patent is valid and would be in-  
11 fringed, the period during which an application may  
12 not be approved under section 505(c)(3) or section  
13 505(j)(4)(B) shall be extended by a period of six  
14 months after the date the patent expires (including  
15 any patent extensions).

16 “(d) CONDUCT OF PEDIATRIC STUDIES.—

17 “(1) AGREEMENT FOR STUDIES.—The Sec-  
18 retary may, pursuant to the written request for  
19 studies, after consultation with

20 “(A) the sponsor of an application for an  
21 investigational new drug under section 505(i),

22 “(B) the sponsor of an application for a  
23 drug under section 505(b)(1), or

24 “(C) the holder of an approved application  
25 for a drug under section 505(b)(1), agree with

1           the sponsor or holder for the conduct of pedi-  
2           atric studies for such drug.

3           “(2) WRITTEN PROTOCOLS TO MEET THE  
4           STUDIES REQUIREMENT.—If the sponsor or holder  
5           and the Secretary agree upon written protocols for  
6           such studies, the studies requirement of subsection  
7           (a) or (c) is satisfied upon the completion of the  
8           studies and submission of the reports thereof in ac-  
9           cordance with the original written request and the  
10          written agreement referred to in (1). Not later than  
11          60 days after the submission of the report of the  
12          studies, the Secretary shall determine if such studies  
13          were or were not conducted in accordance with the  
14          original written request and the written agreement  
15          and reported in accordance with the requirements of  
16          the Secretary for filing and so notify the sponsor or  
17          holder.

18          “(3) OTHER METHODS TO MEET THE STUDIES  
19          REQUIREMENT.—If the sponsor or holder and the  
20          Secretary have not agreed in writing on the proto-  
21          cols for the studies, the studies requirement of sub-  
22          section (a) or (c) is satisfied when such studies have  
23          been completed and the reports accepted by the Sec-  
24          retary. Not later than 90 days after the submission  
25          of the reports of the studies, the Secretary shall ac-

1       cept or reject such reports and so notify the sponsor  
2       or holder. The Secretary's only responsibility in ac-  
3       cepting or rejecting the reports shall be to deter-  
4       mine, within 90 days, whether the studies fairly re-  
5       spond to the written request, whether such studies  
6       have been conducted in accordance with commonly  
7       accepted scientific principles and protocols, and  
8       whether such studies have been reported in accord-  
9       ance with the requirements of the Secretary for fil-  
10      ing.

11       “(e) DELAY OF EFFECTIVE DATE FOR CERTAIN AP-  
12      PLICATIONS; PERIOD OF MARKET EXCLUSIVITY.—If the  
13      Secretary determines that the acceptance or approval of  
14      an application under section 505(b)(2) or 505(j) for a  
15      drug may occur after submission of reports of pediatric  
16      studies under this section, which were submitted prior to  
17      the expiration of the patent (including any patent exten-  
18      sion) or market exclusivity protection, but before the Sec-  
19      retary has determined whether the requirements of sub-  
20      section (d) have been satisfied, the Secretary shall delay  
21      the acceptance or approval under section 505(b)(2) or  
22      505(j), respectively, until the determination under sub-  
23      section (d) is made, but such delay shall not exceed 90  
24      days. In the event that requirements of this section are  
25      satisfied, the applicable period of market exclusivity re-



1 ferred to in subsection (a) or (c) shall be deemed to have  
2 been running during the period of delay.

3       “(f) NOTICE OF DETERMINATIONS ON STUDIES RE-  
4 QUIREMENT.—The Secretary shall publish notice of any  
5 determination that the requirements of subsection (d)  
6 have been met and that submissions and approvals under  
7 section 505(b)(2) or (j) for a drug will be subject to the  
8 provisions of this section.

9       “(g) DEFINITIONS.—As used in this section, the term  
10 ‘pediatric studies’ or ‘studies’ means at least one clinical  
11 investigation (that, at the Secretary’s discretion, may in-  
12 clude pharmacokinetic studies) in pediatric age-groups in  
13 which a drug is anticipated to be used.

14       “(h) LIMITATION.—The holder of an approved appli-  
15 cation for a new drug that has already received six months  
16 of market exclusivity under subsection (a) or subsection  
17 (c) may, if otherwise eligible, obtain six months of market  
18 exclusivity under subsection (c)(1)(B) for a supplemental  
19 application; however the holder is not eligible for exclusiv-  
20 ity under subsection (c)(2).”

21       “(i) SUNSET.—No period of market exclusivity shall  
22 be granted under this section based on studies commenced  
23 after January 1, 2004. The Secretary shall conduct a  
24 study and report to Congress not later than January 1,  
25 2003 based on the experience under the program. The

1 study and report shall examine all relevant issues, includ-  
2 ing—

3           “(1) the effectiveness of the program in improv-  
4           ing information about important pediatric uses for  
5           approved drugs;

6           “(2) the adequacy of the incentive provided  
7           under this section;

8           “(3) the economic impact of the program; and

9           “(4) any suggestions for modification that the  
10          Secretary deems appropriate.”.

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