

104TH CONGRESS
2^D SESSION

H. R. 4277

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.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 1996

Mr. GREENWOOD (for himself, Mr. WAXMAN, Mr. BURR, Mr. TOWNS, Mr. KLUG, Mr. FRANKS of New Jersey, and Mr. HALL of Texas) introduced the following bill; which was referred to the Committee on Commerce

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 (e)(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 (e)(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 (e)(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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