

103<sup>D</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 2010

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

APRIL 12 (legislative day, APRIL 11), 1994

Mrs. KASSEBAUM (for herself, Mr. DODD, Mr. HATCH, 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. 501 et seq.) is amended by inserting after  
4 section 505 the following new section:

5 “PEDIATRIC STUDIES FOR NEW DRUG APPLICATIONS

6 “SEC. 505A. (a) If an application submitted under  
7 section 505(b)(1) is approved on or after the date of en-  
8 actment of this section, and such application includes re-  
9 ports of pediatric studies described and requested in sub-  
10 section (c), and such studies are completed and the reports  
11 thereof submitted in accordance with subsection (c)(2) or  
12 completed and the reports thereof accepted in accordance  
13 with subsection (c)(3), the Secretary may not make the  
14 approval of an application submitted under section  
15 505(b)(2) or section 505(j) which refers to the drug for  
16 which the section 505(b)(1) approval is granted effective  
17 prior to the expiration of 6 months from the earliest date  
18 on which the approval of such application for the drug  
19 under section 505(b)(2) or section 505(j), respectively,  
20 could otherwise be made effective under the applicable  
21 provisions of this chapter.

22 “(b) If the Secretary makes a written request for pe-  
23 diatric studies described in subsection (c) to the holder  
24 of an approval under section 505(b)(1) for a drug, and  
25 such studies are completed and the reports thereof submit-  
26 ted in accordance with subsection (c)(2) or completed and

1 the reports thereof accepted in accordance with subsection  
2 (c)(3), the Secretary may not make the approval of an  
3 application submitted under section 505(b)(2) or section  
4 505(j) which refers to the drug subject to the section  
5 505(b)(1) approval effective prior to the expiration of 6  
6 months from the earliest date on which an approval of  
7 such application under section 505(b)(2) or section 505(j),  
8 respectively, could otherwise be made effective under the  
9 applicable provisions of this chapter. Nothing in this sub-  
10 section shall affect the ability of the Secretary to make  
11 effective a section 505(b)(2) or section 505(j) approval for  
12 a subject drug if such approval is proper under such sub-  
13 section and is made effective prior to the submission of  
14 the reports of pediatric studies described in subsection (c).

15       “(c)(1) The Secretary may, pursuant to a written re-  
16 quest for studies after consultation with the sponsor of  
17 an application or holder of an approval for a drug under  
18 section 505(b)(1), agree with the sponsor or holder for the  
19 conduct of pediatric studies for such drug.

20       “(2) If the sponsor or holder and the Secretary agree  
21 upon written protocols for such studies, the studies re-  
22 quirement of subsection (a) or (b) is satisfied upon the  
23 completion of the studies in accordance with the protocols  
24 and the submission of the reports thereof to the Secretary.  
25 Within 60 days after the submission of the report of the

1 studies, the Secretary shall determine if such studies were  
2 or were not conducted in accordance with the written pro-  
3 tocols and reported in accordance with the Secretary's re-  
4 quirements for filing and so notify the sponsor or holder.

5       “(3) If the sponsor or holder and the Secretary have  
6 not agreed in writing on the protocols for the studies, the  
7 studies requirement of subsection (a) or (b) is satisfied  
8 when such studies have been completed and the reports  
9 accepted by the Secretary. Within 90 days after the sub-  
10 mission of the reports of the studies, the Secretary shall  
11 accept or reject such reports and so notify the sponsor  
12 or holder. The Secretary's only responsibility in accepting  
13 or rejecting the reports shall be to determine, within 90  
14 days, that the studies fairly respond to the written re-  
15 quest, that such studies have been conducted in accord-  
16 ance with commonly accepted scientific principles and pro-  
17 tocols, and that such studies have been reported in accord-  
18 ance with the Secretary's requirements for filing.

19       “(4) As used in this section, ‘pediatric studies’ or  
20 ‘studies’ means at least 1 human clinical investigation in  
21 a population of adolescent age or younger. At the Sec-  
22 retary's discretion, pharmacokinetic studies may be con-  
23 sidered as clinical investigations.

24       “(d) If the Secretary determines that an approval of  
25 an application under section 505(b)(2) or section 505(j)

1 for a drug may be made effective after submission of re-  
2 ports of pediatric studies under this section but before the  
3 Secretary has determined whether the requirements of  
4 subsection (c) have been satisfied, the Secretary may delay  
5 the effective date of any approval under section 505(b)(2)  
6 or section 505(j), respectively, until the determination  
7 under subsection (c) is made, but such delay shall not ex-  
8 ceed 90 days. In the event that the requirements of this  
9 section are satisfied, the 6-month period referred to in  
10 subsection (a) or (b) shall be deemed to have begun on  
11 the date an approval of an application under section  
12 505(b)(2) or section 505(j), respectively, would have been  
13 permitted absent action under this subsection.

14       “(e) The Secretary shall publish notice of any deter-  
15 mination that the requirements of subsection (c)(2) or  
16 (c)(3) have been met and that approvals for the drug will  
17 be subject to deferred effective dates under this section.”.

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