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103D CONGRESS
2D SESSION

H. R. 4427

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

MAY 16, 1994

Mr. KREIDLER (for himself, Mr. ROWLAND, Mrs. UNSOELD, and Mr. SWIFT) 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 to allow for additional deferred effective dates for approval of applications under the new drugs provisions, 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 ''Better Pharmaceuticals for Children Act''.

SEC. 2. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 501 et seq.) is amended by inserting after section 505 the following new section:

''PEDIATRIC STUDIES FOR NEW DRUG APPLICATIONS

''SEC. 505A. (a) If an application submitted under section 505(b)(1) is approved on or after the date of enactment of this section, and such application includes reports of pediatric studies described and requested in subsection (c), and such studies are completed and the reports thereof submitted in accordance with subsection (c)(2) or completed and the reports thereof accepted in accordance with subsection (c)(3), the Secretary may not make the approval of an application submitted under section 505(b)(2) or section 505(j) which refers to the drug for which the section 505(b)(1) approval is granted effective prior to the expiration of 6 months from the earliest date on which the approval of such application for the drug under section 505(b)(2) or section 505(j), respectively, could otherwise be made effective under the applicable provisions of this chapter.

''(b) If the Secretary makes a written request for pediatric studies described in subsection (c) to the holder of an approval under section 505(b)(1) for a drug, and such studies are completed and the reports thereof submitted in accordance with subsection (c)(2) or completed and

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

''(c)(1) The Secretary may, pursuant to a written request for studies after consultation with the sponsor of an application or holder of an approval for a drug under section 505(b)(1), agree with the sponsor or holder for the conduct of pediatric studies for such drug.

''(2) If the sponsor or holder and the Secretary agree upon written protocols for such studies, the studies requirement of subsection (a) or (b) is satisfied upon the completion of the studies in accordance with the protocols and the submission of the reports thereof to the Secretary. Within 60 days after the submission of the report of the

studies, the Secretary shall determine if such studies were or were not conducted in accordance with the written protocols and reported in accordance with the Secretary's requirements for filing and so notify the sponsor or holder.

''(3) If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (b) is satisfied when such studies have been completed and the reports accepted by the Secretary. Within 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within 90 days, that the studies fairly respond to the written request, that such studies have been conducted in accordance with commonly accepted scientific principles and protocols, and that such studies have been reported in accordance with the Secretary's requirements for filing.

''(4) As used in this section, 'pediatric studies' or 'studies' means at least 1 human clinical investigation in a population of adolescent age or younger. At the Secretary's discretion, pharmacokinetic studies may be considered as clinical investigations.

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

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

''(e) The Secretary shall publish notice of any determination that the requirements of subsection (c)(2) or (c)(3) have been met and that approvals for the drug will be subject to deferred effective dates under this section.''.

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