

107TH CONGRESS
2D SESSION

H. R. 4730

To amend the Federal Food, Drug, and Cosmetic Act to require labeling containing information applicable to pediatric patients.

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2002

Mr. WAXMAN (for himself, Ms. DeLAURO, Ms. ESHOO, Mr. DINGELL, and Mr. BROWN of Ohio) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require labeling containing information applicable to pediatric patients.

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. PEDIATRIC LABELING OF DRUGS AND BIOLOGI-**
4 **CAL PRODUCTS**

5 (a) IN GENERAL.—Subchapter A of chapter V of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
7 et seq.) is amended by inserting after section 505A the
8 following:

1 **“SEC. 505B. PEDIATRIC LABELING OF DRUGS AND BIOLOGI-**
2 **CAL PRODUCTS.**

3 “(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

4 “(1) IN GENERAL.—A person that submits an
5 application (or supplement to an application)—

6 “(A) under section 505 for a new active in-
7 gredient, new indication, new dosage form, new
8 dosing regimen, or new route of administration;
9 or

10 “(B) under section 351 of the Public
11 Health Service Act (42 U.S.C. 262) for a bio-
12 logical product license;
13 shall submit with the application the assessments de-
14 scribed in paragraph (2).

15 “(2) ASSESSMENTS.—

16 “(A) IN GENERAL.—The assessments re-
17 ferred to in paragraph (1) shall contain data,
18 gathered using appropriate formulations, that
19 are adequate—

20 “(i) to assess the safety and effective-
21 ness of the drug, or the biological product
22 licensed under section 351 of the Public
23 Health Service Act (42 U.S.C. 262), for
24 the claimed indications in all relevant pedi-
25 atric subpopulations; and

1 “(ii) to support dosing and adminis-
2 tration for each pediatric subpopulation for
3 which the drug, or the biological product li-
4 censed under section 351 of the Public
5 Health Service Act (42 U.S.C. 262), is
6 safe and effective.

7 “(B) SIMILAR COURSE OF DISEASE OR
8 SIMILAR EFFECT OF DRUG OR BIOLOGICAL
9 PRODUCT.—If the course of the disease and the
10 effects of the drug are sufficiently similar in
11 adults and pediatric patients, the Secretary may
12 conclude that pediatric effectiveness can be ex-
13 trapolated from adequate and well-controlled
14 studies in adults, usually supplemented with
15 other information obtained in pediatric patients,
16 such as pharmacokinetic studies.

17 “(3) DEFERRAL.—On the initiative of the Sec-
18 retary or at the request of the applicant, the Sec-
19 retary may defer submission of some or all assess-
20 ments required under paragraph (1) until a specified
21 date after approval of the drug or issuance of the li-
22 cense for a biological product if—

23 “(A) the Secretary finds that—

1 “(i) the drug or biological product is
2 ready for approval for use in adults before
3 pediatric studies are complete; or

4 “(ii) pediatric studies should be de-
5 layed until additional safety or effective-
6 ness data have been collected; and

7 “(B) the applicant submits to the
8 Secretary—

9 “(i) a certified description of the
10 planned or ongoing studies; and

11 “(ii) evidence that the studies are
12 being conducted or will be conducted with
13 due diligence.

14 “(b) MARKETED DRUGS AND BIOLOGICAL PROD-
15 UCTS.—After providing notice and an opportunity for
16 written response and a meeting, which may include an ad-
17 visory committee meeting, the Secretary may by order re-
18 quire the holder of an approved application relating to a
19 drug under section 505 or the holder of a license for a
20 biological product under section 351 of the Public Health
21 Service Act (42 U.S.C. 262) to submit by a specified date
22 the assessments described in subsection (a) if the Sec-
23 retary finds that—

1 “(1)(A) the drug or biological product is used
2 for a substantial number of pediatric patients for
3 the labeled indications; and

4 “(B) the absence of adequate labeling could
5 pose significant risks to pediatric patients; or

6 “(2)(A) there is reason to believe that the drug
7 or biological product would represent a meaningful
8 therapeutic benefit over existing therapies for pedi-
9 atric patients for 1 or more of the claimed indica-
10 tions; and

11 “(B) the absence of adequate labeling could
12 pose significant risks to pediatric patients.

13 “(c) DELAY IN SUBMISSION OF ASSESSMENTS.—If a
14 person delays the submission of assessments relating to
15 a drug or biological product beyond a date specified in
16 subsection (a) or (b)—

17 “(1) the drug or biological product—

18 “(A) shall be deemed to be misbranded;

19 “(B) shall be subject to action under sec-
20 tions 302 and 304; and

21 “(C) shall not be subject to action under
22 section 303; and

23 “(2) the delay shall not be the basis for a pro-
24 ceeding to withdraw approval for a drug under sec-
25 tion 505(e) or revoke the license for a biological

1 product under section 351 of the Public Health
2 Service Act (42 U.S.C. 262).

3 “(d) WAIVERS.—

4 “(1) FULL WAIVER.—At the request of an ap-
5 plicant, the Secretary shall grant a full waiver, as
6 appropriate, of the requirement to submit assess-
7 ments under subsection (a) or (b) if—

8 “(A) necessary studies are impossible or
9 highly impracticable;

10 “(B) there is evidence strongly suggesting
11 that the drug or biological product would be in-
12 effective or unsafe in all pediatric age groups;
13 or

14 “(C)(i) the drug or biological product—

15 “(I) does not represent a meaningful
16 therapeutic benefit over existing therapies
17 for pediatric patients; and

18 “(II) is not likely to be used for a
19 substantial number of pediatric patients;
20 and

21 “(ii) the absence of adequate labeling
22 would not pose significant risks to pediatric pa-
23 tients.

24 “(2) PARTIAL WAIVER.—At the request of an
25 applicant, the Secretary shall grant a partial waiver,

1 as appropriate, of the requirement to submit assess-
2 ments under subsection (a) with respect to a specific
3 pediatric subpopulation if—

4 “(A) any of the grounds stated in para-
5 graph (1) applies to that subpopulation; or

6 “(B) the applicant demonstrates that rea-
7 sonable attempts to produce a pediatric formu-
8 lation necessary for that subpopulation have
9 failed.

10 “(3) LABELING REQUIREMENT.—If the Sec-
11 retary grants a full or partial waiver because there
12 is evidence that a drug or biological product would
13 be ineffective or unsafe in pediatric populations, the
14 information shall be included in the labeling for the
15 drug or biological product.

16 “(e) MEETINGS.—The Secretary shall meet at appro-
17 priate times in the investigational new drug process with
18 the sponsor to discuss background information that the
19 sponsor shall submit on plans and timelines for pediatric
20 studies, or any planned request for waiver or deferral of
21 pediatric studies.”.

22 (b) CONFORMING AMENDMENTS.—

23 (1) Section 505(b)(1) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) is
25 amended in the second sentence—

1 (A) by striking “and (F)” and inserting
2 “(F)”; and

3 (B) by striking the period at the end and
4 inserting “, and (G) any assessments required
5 under section 505B.”.

6 (2) Section 505A(h) of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 355a(h)) is amended—

8 (A) in the subsection heading, by striking
9 “REGULATIONS” and inserting “PEDIATRIC
10 STUDY REQUIREMENTS”; and

11 (B) by striking “pursuant to regulations
12 promulgated by the Secretary” and inserting
13 “by a provision of law (including a regulation)
14 other than this section”.

15 (3) Section 351(a)(2) of the Public Health
16 Service Act (42 U.S.C. 262(a)(2)) is amended—

17 (A) by redesignating subparagraph (B) as
18 subparagraph (C); and

19 (B) by inserting after subparagraph (A)
20 the following:

21 “(B) PEDIATRIC STUDIES.—A person that
22 submits an application for a license under this
23 paragraph shall submit to the Secretary as part
24 of the application any assessments required

1 under section 505B of the Federal Food, Drug,
2 and Cosmetic Act.”.

3 (c) FINAL RULE.—Except to the extent that the final
4 rule is inconsistent with the amendment made by sub-
5 section (a), the final rule promulgating regulations requir-
6 ing manufacturers to assess the safety and effectiveness
7 of new drugs and biological products in pediatric patients
8 (63 Fed. Reg. 66632 (December 2, 1998)), shall be con-
9 sidered to implement the amendment made by subsection
10 (a).

11 (d) NO EFFECT ON AUTHORITY.—Section 505B of
12 the Federal Food, Drug, and Cosmetic Act (as added by
13 subsection (a)) does not affect whatever existing authority
14 the Secretary of Health and Human Services has to re-
15 quire pediatric assessments regarding the safety and effi-
16 cacy of drugs and biological products in addition to the
17 assessments required under that section. The authority,
18 if any, of the Secretary of Health and Human Services
19 regarding specific populations other than the pediatric
20 population shall be exercised in accordance with the Fed-
21 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
22 seq.) as in effect on the day before the date of enactment
23 of this Act.

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