Calendar No. 547

107TH CONGRESS
2D SESSION

S. 2394

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

IN THE SENATE OF THE UNITED STATES

APRIL 29, 2002

Mrs. CLINTON (for herself, Mr. DEWINE, Mr. DODD, Mrs. MURRAY, Mr. KENNEDY, Mr. BINGAMAN, Mr. KOHL, Mr. REED, Ms. LANDRIEU, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

AUGUST 1, 2002

Reported by Mr. KENNEDY, with an amendment

[Omit the part struck through and insert the part printed in italic]

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PEDIATRIC LABELING OF DRUGS AND BIOLOGICAL PRODUCTS

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

"SEC. 505B. PEDIATRIC LABELING OF DRUGS AND BIOLOGICAL PRODUCTS.

''(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

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

''(A) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

''(B) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a biological product license;

shall submit with the application the assessments described in paragraph (2).

''(2) ASSESSMENTS.—

''(A) IN GENERAL.—The assessments referred to in paragraph (1) shall contain data, gathered using appropriate formulations, that are adequate—

''(i) to assess the safety and effectiveness of the drug, or the biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), for the claimed indications in all relevant pediatric subpopulations; and

''(ii) to support dosing and administration for each pediatric subpopulation for which the drug, or the biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), is safe and effective.

''(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

''(3) DEFERRAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assess-

ments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

"(A) the Secretary finds that—

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

"(ii) pediatric studies should be delayed until additional safety or effectiveness data have been collected; and

"(B) the applicant submits to the Secretary—

"(i) a certified description of the planned or ongoing studies; and

"(ii) evidence that the studies are being conducted or will be conducted with due diligence.

~~"(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—After providing notice and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may by order require the holder of an approved application relating to a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date~~

~~the assessments described in subsection (a) if the Secretary finds that—~~

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

~~"(B) the absence of adequate labeling could pose significant risks to pediatric patients; or~~

~~"(2)(A) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and~~

~~"(B) the absence of adequate labeling could pose significant risks to pediatric patients.~~

"(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

"(1) IN GENERAL.—After providing notice and an opportunity for written response and a meeting, which may include an advisory committee meeting, the Secretary may by order require the holder of an approved application relating to a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262) to submit by a specified date the as-

sessments described in subsection (a) if the Secretary finds that—

"(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

"(ii) the absence of adequate labeling could pose significant risks to pediatric patients; or

"(B)(i) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; and

"(ii) the absence of adequate labeling could pose significant risks to pediatric patients.

"(2) RELATIONSHIP TO OTHER PEDIATRIC PROVISIONS.—

"(A) NO ASSESSMENT WITHOUT WRITTEN REQUEST.—No assessment may be required under paragraph (1) for a drug subject to an approved application under section 505 unless—

"(i) the Secretary has issued a written request for related pediatric studies under section 505A(d) or section 409I of the Public Health Service Act; and

"(ii)(I) if the request was made under section 505A(d)—

"(aa) the recipient of the written request does not agree to the request; or

"(bb) the Secretary does not receive a response as specified under section 505A(d)(4)(A); or

"(II) if the request was made under section 409I of the Public Health Service Act—

"(aa) the recipient of the written request does not agree to the request; or

"(bb) the Secretary does not receive a response as specified under section 409I(c)(2) of that Act.

"(B) NO EFFECT ON OTHER AUTHORITY.—Nothing in this subsection shall be construed to alter any requirement under section 505A(d)(4) or section 409I of the Public Health Service Act. Subject to paragraph (2)(A), nothing in this subsection, section 505A(d)(4), or section 409I or 499 of the Public Health Service Act shall be construed to preclude the Secretary from exercising the authority of the Secretary under this subsection.

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

''(1) the drug or biological product—

''(A) shall be deemed to be misbranded;

''(B) shall be subject to action under sections 302 and 304; and

''(C) shall not be subject to action under section 303; and

''(2) the delay shall not be the basis for a proceeding to withdraw approval for a drug under section 505(e) or revoke the license for a biological product under section 351 of the Public Health Service Act (42 U.S.C. 262).

''(d) WAIVERS.—

''(1) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under subsection (a) or (b) if—

''(A) necessary studies are impossible or highly impracticable;

''(B) there is evidence strongly suggesting that the drug or biological product would be in-

effective or unsafe in all pediatric age groups; or

"(C)(i) the drug or biological product—

"(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

"(II) is not likely to be used for a substantial number of pediatric patients; and

"(ii) the absence of adequate labeling would not pose significant risks to pediatric patients.

"(2) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under subsection (a) with respect to a specific pediatric subpopulation if—

"(A) any of the grounds stated in paragraph (1) applies to that subpopulation; or

"(B) the applicant demonstrates that reasonable attempts to produce a pediatric formulation necessary for that subpopulation have failed.

"(3) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there

is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

''(e) MEETINGS.—The Secretary shall meet at appropriate times in the investigational new drug process with the sponsor to discuss background information that the sponsor shall submit on plans and timelines for pediatric studies, or any planned request for waiver or deferral of pediatric studies.''.

(b) CONFORMING AMENDMENTS.—

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

(A) by striking ''and (F)'' and inserting ''(F)''; and

(B) by striking the period at the end and inserting '', and (G) any assessments required under section 505B.''.

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

(A) in the subsection heading, by striking ''REGULATIONS'' and inserting ''PEDIATRIC STUDY REQUIREMENTS''; and

(B) by striking ''pursuant to regulations promulgated by the Secretary'' and inserting ''by a provision of law (including a regulation) other than this section''.

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

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

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

''(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.''.

(c) FINAL RULE.—Except to the extent that the final rule is inconsistent with the amendment made by subsection (a), the final rule promulgating regulations requiring manufacturers to assess the safety and effectiveness of new drugs and biological products in pediatric patients (63 Fed. Reg. 66632 (December 2, 1998)), shall be considered to implement the amendment made by subsection (a).

(d) NO EFFECT ON AUTHORITY.—Section 505B of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)) does not affect whatever existing authority the Secretary of Health and Human Services has to require pediatric assessments regarding the safety and efficacy of drugs and biological products in addition to the assessments required under that section. The authority, if any, of the Secretary of Health and Human Services regarding specific populations other than the pediatric population shall be exercised in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as in effect on the day before the date of enactment of this Act.

SEC. 2. TECHNICAL CORRECTION.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended in subparagraphs (A) and (B) of subsection (b)(2) and subparagraphs (A) and (B) of subsection (c)(2) by striking ''505(j)(4)(B)'' and inserting ''505(j)(5)(B)''.

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