

substitution in introductory provisions of subsec. (n), to reflect the probable intent of Congress.

Pub. L. 107-109, §19(2), (3), redesignated subsec. (j) as (n). Former subsec. (n) redesignated (k).

Pub. L. 107-109, §10, added subsec. (n).

Subsec. (o). Pub. L. 107-109, §19(2), (3), redesignated subsec. (o) as (l).

Pub. L. 107-109, §11(a), added subsec. (o).

EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110-85, title V, §502(a)(2), Sept. 27, 2007, 121 Stat. 885, provided that:

“(A) IN GENERAL.—The amendment made by this subsection [amending this section] shall apply to written requests under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) issued on or after the date of the enactment of this Act [Sept. 27, 2007].

“(B) CERTAIN WRITTEN REQUESTS.—A written request issued under section 505A of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this Act, which has been accepted and for which no determination under subsection (d)(2) of such section has been made before such date of enactment, shall be subject to such section 505A, except that such written requests shall be subject to subsections (d)(2)(A)(ii), (e)(1) and (2), (f), (i)(2)(A), (j), (k)(1), (l)(1), and (n) of section 505A of the Federal Food, Drug, and Cosmetic Act, as in effect on or after the date of the enactment of this Act.”

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108-155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108-155, set out as an Effective Date note under section 355c of this title.

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107-109, §11(b), Jan. 4, 2002, 115 Stat. 1416, provided that: “The amendment made by subsection (a) [amending this section] takes effect on the date of enactment of this Act [Jan. 4, 2002], including with respect to applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that are approved or pending on that date.”

CONSTRUCTION OF 2007 AMENDMENTS ON PEDIATRIC STUDIES

Pub. L. 110-85, title IX, §901(e), Sept. 27, 2007, 121 Stat. 942, provided that: “This title [enacting sections 353b, 355-1, 355e, 360a, and 360bbb-6 of this title, amending sections 331, 333, 334, 352, 355, and 381 of this title and section 262 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 331, 352, and 355 of this title] and the amendments made by this title may not be construed as affecting the authority of the Secretary of Health and Human Services to request pediatric studies under section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a] or to require such studies under section 505B of such Act [21 U.S.C. 355c].”

REPORT ON PEDIATRIC EXCLUSIVITY PROGRAM

Pub. L. 107-109, §16, Jan. 4, 2002, 115 Stat. 1421, as amended by Pub. L. 108-155, §3(b)(4), Dec. 3, 2003, 117 Stat. 1942, required the Comptroller General, not later than Oct. 1, 2006, and in consultation with the Secretary of Health and Human Services, to submit to Congress a report on specified issues concerning the effectiveness of the pediatric exclusivity program.

STUDY BY GENERAL ACCOUNTING OFFICE

Pub. L. 107-109, §18(b), Jan. 4, 2002, 115 Stat. 1423, required the Comptroller General, not later than Jan. 10, 2003, to conduct a study relating to the representation of children of ethnic and racial minorities in studies under section 355a of this title and to submit a report to Congress describing the findings of the study.

§ 355b. Adverse-event reporting

(a) Toll-free number in labeling

Not later than one year after January 4, 2002, the Secretary of Health and Human Services shall promulgate a final rule requiring that the labeling of each drug for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355] (regardless of the date on which approved) include the toll-free number maintained by the Secretary for the purpose of receiving reports of adverse events regarding drugs and a statement that such number is to be used for reporting purposes only, not to receive medical advice. With respect to the final rule:

(1) The rule shall provide for the implementation of such labeling requirement in a manner that the Secretary considers to be most likely to reach the broadest consumer audience.

(2) In promulgating the rule, the Secretary shall seek to minimize the cost of the rule on the pharmacy profession.

(3) The rule shall take effect not later than 60 days after the date on which the rule is promulgated.

(b) Drugs with pediatric market exclusivity

(1) In general

During the one year beginning on the date on which a drug receives a period of market exclusivity under 505A¹ of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a], any report of an adverse event regarding the drug that the Secretary of Health and Human Services receives shall be referred to the Office of Pediatric Therapeutics established under section 393a of this title. In considering the report, the Director of such Office shall provide for the review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such subcommittee² regarding whether the Secretary should take action under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] in response to the report.

(2) Rule of construction

Paragraph (1) may not be construed as restricting the authority of the Secretary of Health and Human Services to continue carrying out the activities described in such paragraph regarding a drug after the one-year period described in such paragraph regarding the drug has expired.

(Pub. L. 107-109, §17, Jan. 4, 2002, 115 Stat. 1422; Pub. L. 108-155, §3(b)(5), Dec. 3, 2003, 117 Stat. 1942.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section was enacted as part of the Best Pharmaceuticals for Children Act, and not as part of the Fed-

¹ So in original. Probably should be preceded by “section”.

² So in original. Probably should be “Committee”.

eral Food, Drug, and Cosmetic Act which comprises this chapter.

AMENDMENTS

2003—Subsec. (b)(1). Pub. L. 108-155 struck out “Advisory Subcommittee of the Anti-Infective Drugs” before “Advisory Committee”.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108-155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108-155, set out as an Effective Date note under section 355c of this title.

§ 355c. Research into pediatric uses for drugs and biological products

(a) New drugs and biological products

(1) In general

A person that submits, on or after September 27, 2007, an application (or supplement to an application)—

(A) under section 355 of this title for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration, or

(B) under section 262 of title 42 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration,

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 for each age group for which the assessment is required, that are adequate—

(i) to assess the safety and effectiveness of the drug or the biological product 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 is safe and effective.

(B) Similar course of disease or similar effect of drug or biological product

(i) In general

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.

(ii) Extrapolation between age groups

A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.

(iii) Information on extrapolation

A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under

section 355 of this title or section 262 of title 42.

(3) Deferral

(A) In general

On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1) until a specified date after approval of the drug or issuance of the license for a biological product if—

(i) the Secretary finds that—

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

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

(III) there is another appropriate reason for deferral; and

(ii) the applicant submits to the Secretary—

(I) certification of the grounds for deferring the assessments;

(II) a description of the planned or ongoing studies;

(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

(IV) a timeline for the completion of such studies.

(B) Annual review

(i) In general

On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary the following information:

(I) Information detailing the progress made in conducting pediatric studies.

(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.

(ii) Public availability

The information submitted through the annual review under clause (i) shall promptly be made available to the public in an easily accessible manner, including through the Web site of the Food and Drug Administration.

(4) Waivers

(A) Full waiver

On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would