

(C) The Secretary may establish categories of such changes and designate categories to which subparagraph (A) applies and categories to which subparagraph (B) applies.

(2) Changes not requiring supplemental application

(A) Submission of report

A holder making a manufacturing change to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which shall contain such information as the Secretary determines to be appropriate, and which shall include the information developed under subsection (b) of this section by the holder in validating the effects of the change. The report shall be submitted by such date as the Secretary may specify.

(B) Authority regarding annual reports

In the case of a holder that during a single year makes more than one manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph (A) authorize the holder to comply with such subparagraph by submitting a single report for the year that provides the information required in such subparagraph for all the changes made by the holder during the year.

(3) Changes requiring supplemental application

(A) Submission of supplemental application

The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information as the Secretary determines to be appropriate, which shall include the information developed under subsection (b) of this section by the holder in validating the effects of the change.

(B) Authority for distribution

In the case of a manufacturing change to which paragraph (1)(B) applies:

(i) The holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under such paragraph, unless the Secretary notifies the holder within such 30-day period that prior approval of the application is required before distribution may be commenced.

(ii) The Secretary may designate a category of such changes for the purpose of providing that, in the case of a change that is in such category, the holder involved may commence distribution of the drug involved upon the receipt by the Secretary of a supplemental application for the change.

(iii) If the Secretary disapproves the supplemental application, the Secretary may order the manufacturer to cease the distribution of the drugs that have been made with the manufacturing change.

(June 25, 1938, ch. 675, §506A, as added Pub. L. 105-115, title I, §116(a), Nov. 21, 1997, 111 Stat. 2313.)

EFFECTIVE DATE

Section 116(b) of Pub. L. 105-115 provided that: “The amendment made by subsection (a) [enacting this sec-

tion] takes effect upon the effective date of regulations promulgated by the Secretary of Health and Human Services to implement such amendment, or upon the expiration of the 24-month period beginning on the date of the enactment of this Act [Nov. 21, 1997], whichever occurs first.”

§ 356b. Reports of postmarketing studies

(a) Submission

(1) In general

A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

(2) Agreements prior to effective date

Any agreement entered into between the Secretary and a sponsor of a drug, prior to November 21, 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

(b) Consideration of information as public information

Any information pertaining to a report described in subsection (a) of this section shall be considered to be public information to the extent that the information is necessary—

(1) to identify the sponsor; and

(2) to establish the status of a study described in subsection (a) of this section and the reasons, if any, for any failure to carry out the study.

(c) Status of studies and reports

The Secretary shall annually develop and publish in the Federal Register a report that provides information on the status of the postmarketing studies—

(1) that sponsors have entered into agreements to conduct; and

(2) for which reports have been submitted under subsection (a)(1) of this section.

(d) Disclosure

If a sponsor fails to complete an agreed upon study required by this section by its original or otherwise negotiated deadline, the Secretary shall publish a statement on the Internet site of the Food and Drug Administration stating that the study was not completed and, if the reasons for such failure to complete the study were not satisfactory to the Secretary, a statement that such reasons were not satisfactory to the Secretary.

(e) Notification

With respect to studies of the type required under section 356(b)(2)(A) of this title or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as each of such sections was in effect on the day before the effective date of this

subsection, the Secretary may require that a sponsor who, for reasons not satisfactory to the Secretary, fails to complete by its deadline a study under any of such sections of such type for a drug or biological product (including such a study conducted after such effective date) notify practitioners who prescribe such drug or biological product of the failure to complete such study and the questions of clinical benefit, and, where appropriate, questions of safety, that remain unanswered as a result of the failure to complete such study. Nothing in this subsection shall be construed as altering the requirements of the types of studies required under section 356(b)(2)(A) of this title or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as so in effect, or as prohibiting the Secretary from modifying such sections of title 21 of such Code to provide for studies in addition to those of such type.

(June 25, 1938, ch. 675, §506B, as added Pub. L. 105-115, title I, §130(a), Nov. 21, 1997, 111 Stat. 2331; amended Pub. L. 107-188, title V, §506, June 12, 2002, 116 Stat. 693.)

REFERENCES IN TEXT

The effective date of this subsection, referred to in subsec. (e), is Oct. 1, 2002, see Effective Date of 2002 Amendment note set out below.

AMENDMENTS

2002—Subsecs. (d), (e). Pub. L. 107-188 added subsecs. (d) and (e).

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107-188, title V, §508, June 12, 2002, 116 Stat. 694, provided that: “The amendments made by this subtitle [subtitle A (§§501-509) of title V of Pub. L. 107-188, amending this section and sections 379g and 379h of this title] shall take effect October 1, 2002.”

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

REPORT TO CONGRESSIONAL COMMITTEES

Pub. L. 105-115, title I, §130(b), Nov. 21, 1997, 111 Stat. 2331, provided that not later than Oct. 1, 2001, the Secretary was to submit to Congress a report containing a summary of the reports submitted under section 356b of this title and an evaluation and legislative recommendations relating to postmarketing studies of drugs.

§ 356c. Discontinuance of life saving product

(a) In general

A manufacturer that is the sole manufacturer of a drug—

- (1) that is—
 - (A) life-supporting;
 - (B) life-sustaining; or
 - (C) intended for use in the prevention of a debilitating disease or condition;

(2) for which an application has been approved under section 355(b) or 355(j) of this title; and

(3) that is not a product that was originally derived from human tissue and was replaced by a recombinant product,

shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

(b) Reduction in notification period

The notification period required under subsection (a) of this section for a manufacturer may be reduced if the manufacturer certifies to the Secretary that good cause exists for the reduction, such as a situation in which—

(1) a public health problem may result from continuation of the manufacturing for the 6-month period;

(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer;

(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11; or

(6) the manufacturer can continue the distribution of the drug involved for 6 months.

(c) Distribution

To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs described in subsection (a) of this section to appropriate physician and patient organizations.

(June 25, 1938, ch. 675, §506C, as added Pub. L. 105-115, title I, §131(a), Nov. 21, 1997, 111 Stat. 2332.)

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§ 357. Repealed. Pub. L. 105-115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325

Section, act June 25, 1938, ch. 675, §507, as added July 6, 1945, ch. 281, §3, 59 Stat. 463; amended Mar. 10, 1947, ch. 16, §3, 61 Stat. 12; July 13, 1949, ch. 305, §2, 63 Stat. 409; Aug. 5, 1953, ch. 334, §2, 67 Stat. 389; Pub. L. 87-781, title I, §§105(a), (b), (d)-(f), 106(a), (b), Oct. 10, 1962, 76 Stat. 785, 786, 787; Pub. L. 90-399, §105(b), July 13, 1968, 82 Stat. 352; Pub. L. 102-300, §6(b)(2), June 16, 1992, 106 Stat. 240; Pub. L. 103-80, §3(p), Aug. 13, 1993, 107 Stat. 777, related to certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug.

§ 358. Authority to designate official names

(a) Necessity or desirability; use in official compendiums; infringement of trademarks

The Secretary may designate an official name for any drug or device if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any drug or device shall be the only official name of that drug or device used in any official compendium published after such name has been prescribed or for any other purpose of this chapter. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

(b) Review of names in official compendiums

Within a reasonable time after October 10, 1962, and at such other times as he may deem