

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) 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.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Pub. L. 105-115, title I, § 116(b), Nov. 21, 1997, 111 Stat. 2315, provided that: "The amendment made by subsection (a) [enacting this section] 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) Accelerated approval

Notwithstanding paragraph (1), a sponsor of a drug approved pursuant to accelerated approval shall submit to the Secretary a report of the progress of any study required under section 356(c) of this title, including progress toward enrollment targets, milestones, and other information as required by the Secretary, not later than 180 days after the approval of such drug and not less frequently than every 180 days thereafter, until the study is completed or terminated. The Secretary shall promptly publish on the website of the Food and Drug Administration, in an easily searchable format, the information reported under this paragraph.

(3) 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) 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) 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).

(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(c)(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(c)(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; Pub. L. 112-144, title IX, §902(c), July 9, 2012, 126 Stat. 1088; Pub. L. 117-328, div. FF, title III, §3210(b), Dec. 29, 2022, 136 Stat. 5823.)

Editorial Notes

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

2022—Subsec. (a)(2), (3). Pub. L. 117-328 added par. (2) and redesignated former par. (2) as (3).

2012—Subsec. (e). Pub. L. 112-144 substituted “section 356(c)(2)(A) of this title” for “section 356(b)(2)(A) of this title” in two places.

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

Statutory Notes and Related Subsidiaries

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.

CONSTRUCTION OF 2022 AMENDMENT

Nothing in amendment made by Pub. L. 117-328 to be construed to affect ongoing withdrawal proceedings for products approved pursuant to section 356(c) of this title for which a notice of proposed withdrawal has been published in the Federal Register prior to Dec. 29, 2022, see section 3210(f) of Pub. L. 117-328, set out as a note under section 356 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 or interruption in the production of life-saving drugs

(a) In general

A manufacturer of a drug—

(1) that is—

(A) life-supporting;

(B) life-sustaining; or

(C) intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery or any such drug that is critical to the public health during a public health emergency declared by the Secretary under section 247d of title 42; and

(2) that is not a radio pharmaceutical drug product or any other product as designated by the Secretary,

shall notify the Secretary, in accordance with subsection (b), of a permanent discontinuance in the manufacture of the drug or an interruption of the manufacture of the drug that is likely to lead to a meaningful disruption in the supply of that drug in the United States, or a permanent discontinuance in the manufacture of an active pharmaceutical ingredient or an interruption in the manufacture of the active pharmaceutical ingredient of such drug that is likely to lead to a meaningful disruption in the supply of the active pharmaceutical ingredient of such drug, and the reasons for such discontinuance or interruption. Notification under this subsection shall include disclosure of reasons for the discontinuation or interruption, and if applicable, an active pharmaceutical ingredient is a reason for, or risk factor in, such discontinuation or interruption, the source of the active pharmaceutical ingredient and any alternative sources for the active pharmaceutical ingredient known by the manufacturer; whether any associated device used for preparation or administration included in the drug is a reason for, or a risk factor in, such discontinuation or interruption; the expected duration of the interruption; and such other information as the Secretary may require.

(b) Timing

A notice required under subsection (a) shall be submitted to the Secretary—

(1) at least 6 months prior to the date of the discontinuance or interruption; or

(2) if compliance with paragraph (1) is not possible, as soon as practicable.

(c) Distribution

To the maximum extent practicable, the Secretary shall distribute, through such means as the Secretary deems appropriate, information on the discontinuance or interruption of the manufacture of the drugs described in subsection (a) to appropriate organizations, including physician, health provider, and patient organizations, as described in section 356e of this title.

(d) Confidentiality

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.