*** CURRENT THROUGH P.L. 109-467, APPROVED 12/22/2006 ***
*** WITH GAPS OF 109-432, 435 thru 438, 441 thru 462, 465 and 466 ***

21 USCS § 356b

§ 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 the date of enactment of the Food and Drug Administration Modernization Act of 1997 [enacted Nov. 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 506(b)(2)(A) [21 USCS § 356(b)(2)(A)] 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 [effective Oct. 1, 2002], 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 506(b)(2)(A) [21 USCS § 356(b)(2)(A)] 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.

History:

(June 25, 1938, ch 675, Ch. V, Subch A, § 506B, as added Nov. 21, 1997, P.L. 105-115, Title I, Subtitle B, § 130(a), 111 Stat. 2331; June 12, 2002, P.L. 107-188, Title V, Subtitle A, § 506, 116 Stat. 693.)

History; Ancillary Laws and Directives:

1. Effective date of section
2. Amendments
3. Other provisions

1. Effective date of section:

This section took effect 90 days after enactment, pursuant to § 501 of Act Nov. 21, 1997, P.L. 105-115, which appears as 21 USCS § 321 note.

2. Amendments:

2002. Act June 12, 2002 (effective 10/1/2002, as provided by § 508 of such Act, which appears as a note to this section), added subsecs. (d) and (e).

3. Other provisions:

Report to Congressional Committees. Act Nov. 21, 1997, P.L. 105-115, Title I, Subtitle B, § 130(b), 111 Stat. 2331, provides:

"Not later than October 1, 2001, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report containing--

"(1) a summary of the reports submitted under section 506B of the Federal Food, Drug, and Cosmetic Act [this section];

"(2) an evaluation of--

"(A) the performance of the sponsors referred to in such section in fulfilling the agreements with respect to the conduct of postmarketing studies described in such section of such Act [21 USCS §§ 301 et seq.]; and

"(B) the timeliness of the Secretary's review of the postmarketing studies; and

"(3) any legislative recommendations respecting the postmarketing studies.".

Effective date of June 12, 2002 amendments. Act June 12, 2002, P.L. 107-188, Title V, Subtitle A, § 508, 116 Stat. 694, provides: "The amendments made by this subtitle [amending 21 USCS §§ 356b, 379g, and 379h] shall take effect October 1, 2002.".