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21 U.S. Code § 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.