

## **FDA Fact Sheets: Condition of Approval Studies**

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Through review of a Premarket Approval Application (PMA), FDA evaluates the safety and effectiveness of Class III medical devices. To help assure the continued safety and effectiveness of an approved device, in some cases FDA may require a post-approval study, also referred to as condition of approval study. A post-approval study may be a clinical or non-clinical study required at the time of approval and is intended to gather specific information to address questions about the postmarket performance of or experience with an approved medical device.

As a condition of approval for the device, FDA can require continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. The rationale for the requirement, the type of study to be conducted, the number of patients to be evaluated, and the required reports are to be stated by FDA in the PMA approval notification. Through reliance on this type of postmarket control, FDA may consider a reduced amount of premarket data required at the time of PMA submission.

Determinations of the final protocol for the post-approval study and the schedule for study completion are based on agreements between the applicant and FDA during the PMA review. The PMA applicant may be required to submit interim post-approval study reports that are reviewed by epidemiologists in FDA's Office of Surveillance and Biometrics for completeness, adherence to protocol, and evaluation of safety and effectiveness. Through review of final post-approval reports, FDA will determine whether post-approval commitments have been met. A PMA supplement may be required if study outcomes affect device labeling.

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