
21 U.S. Code § 356-1

Accelerated approval of priority countermeasures

(a) In general

The Secretary of Health and Human Services may designate a priority countermeasure as a fast-track product pursuant to section 356 of this title or as a device granted review priority pursuant to section 360e(d)(5)¹ of this title. Such a designation may be made prior to the submission of—

- (1) a request for designation by the sponsor or applicant; or

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