

# 21 U.S. Code § 356h

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## Competitive generic therapies

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### **(a) In general**

The Secretary may, at the request of an applicant of a drug that is designated as a competitive generic therapy pursuant to subsection (b), expedite the development and review of an abbreviated new drug application under section 355(j) of this title for such drug.

### **(b) Designation process**

#### **(1) Request**

The applicant may request the Secretary to designate the drug as a competitive generic therapy.

#### **(2) Timing**

A request under paragraph (1) may be made concurrently with, or at any time prior to, the submission of an abbreviated new drug application for the drug under section 355(j) of this title.

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