

21 U.S. Code § 360cc

Protection for drugs for rare diseases or conditions

(a) Exclusive approval, certification, or license

Except as provided in subsection (b), if the Secretary—

- (1) approves an application filed pursuant to section 355 of this title, or
- (2) issues a license under section 262 of title 42

for a drug designated under section 360bb of this title for a rare disease or condition, the Secretary may not approve another application under section 355 of this title or issue another license under section 262 of title 42 for the same drug for the same disease or condition for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license. Section 355(c)(2) ^[1] of this title does not apply to the refusal to approve an application under the preceding sentence.

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