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## 21 U.S. Code § 360ccc-2

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### Designated new animal drugs for minor use or minor species

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#### **(a) Designation**

- (1) The manufacturer or the sponsor of a new animal drug for a minor use or use in a minor species may request that the Secretary declare that drug a “designated new animal drug”. A request for designation of a new animal drug shall be made before the submission of an application under section 360b(b) of this title or section 360ccc of this title for the new animal drug.
- (2) The Secretary may declare a new animal drug a “designated new animal drug” if—
  - (A) it is intended for a minor use or use in a minor species; and
  - (B) the same drug in the same dosage form for the same intended use is not approved under section 360b or 360ccc of this title or designated under this section at the time the request is made.
- (3) Regarding the termination of a designation—
  - (A) the sponsor of a new animal drug shall notify the Secretary of any decision to discontinue active pursuit of approval under section 360b or 360ccc of this title of an application for a designated new animal drug. The Secretary shall terminate the designation upon such notification;
  - (B) the Secretary may also terminate designation if the Secretary independently determines that the sponsor is not actively pursuing approval under section 360b or 360ccc of this title with due diligence;
  - (C) the sponsor of an approved designated new animal drug shall notify the Secretary of any discontinuance of the manufacture of such new animal drug at least one year before discontinuance. The Secretary shall terminate the designation upon such notification; and
  - (D) the designation shall terminate upon the expiration of any applicable exclusivity period under subsection (c).

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