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# 21 U.S. Code § 379k-1

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## Electronic format for submissions

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### **(a) Drugs and biologics**

#### **(1) In general**

Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 355 of this title or subsection (a) or (k) of section 262 of title 42 shall be submitted in such electronic format as specified by the Secretary in such guidance.

#### **(2) Guidance contents**

In the guidance under paragraph (1), the Secretary may—

- (A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and
- (B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

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