
21 U.S. Code § 356I

Advanced manufacturing technologies designation program

(a) In general

Not later than 1 year after December 29, 2022, the Secretary shall initiate a program under which persons may request designation of an advanced manufacturing technology as described in subsection (b).

(b) Designation process

The Secretary shall establish a process for the designation under this section of methods of manufacturing drugs, including biological products, and active pharmaceutical ingredients of such drugs, as advanced manufacturing technologies. A method of manufacturing, or a combination of manufacturing methods, is eligible for designation as an advanced manufacturing technology if such method or combination of methods incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially improve the manufacturing process for a drug while maintaining equivalent, or providing superior, drug quality, including by—

- (1) reducing development time for a drug using the designated manufacturing method; or
- (2) increasing or maintaining the supply of—
 - (A) a drug that is life-supporting, life-sustaining, or of critical importance to providing health care; or
 - (B) a drug that is on the drug shortage list under section 356e of this title.

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