
21 U.S. Code § 360ddd-1

Regulation of medical gases

(a) Certification of designated medical gases

(1) Submission

Beginning 180 days after July 9, 2012, any person who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce may file with the Secretary a request for certification of a medical gas as a designated medical gas. Any such request shall contain the following information:

- (A) A description of the medical gas.
- (B) The name and address of the sponsor.
- (C) The name and address of the facility or facilities where the medical gas is or will be manufactured.
- (D) Any other information deemed appropriate by the Secretary to determine whether the medical gas is a designated medical gas.

(2) Grant of certification

The certification requested under paragraph (1) is deemed to be granted unless, within 60 days of the filing of such request, the Secretary finds that—

- (A) the medical gas subject to the certification is not a designated medical gas;
- (B) the request does not contain the information required under paragraph (1) or otherwise lacks sufficient information to permit the Secretary to determine that the medical gas is a designated medical gas; or
- (C) denying the request is necessary to protect the public health.

This document is only available to subscribers. Please [log in](#) or [purchase access](#).

[Purchase Login](#)