

## 42 C.F.R. § 11.66

---

### What are potential legal consequences of not complying with the requirements of this part?

---

(a) *Civil or criminal judicial actions.* Failure to comply with the requirements of this part, issued under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)), is a prohibited act under one or more provisions of section 301(jj) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(jj)):

(1) Failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service (42 U.S.C. 282(j)(5)(B)) that all applicable requirements of section 402(j) have been met, or knowingly submitting a false certification under section 402(j)(5)(B), is a prohibited act under section 301(jj)(1) of the Federal Food, Drug, and Cosmetic Act.

This document is only available to subscribers. Please log in or purchase access.

[Purchase Login](#)