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42 C.F.R. § 11.44

When must clinical trial results information be submitted for applicable clinical trials subject to § 11.42?

(a) *Standard submission deadline.* In general, for applicable clinical trials subject to § 11.42, clinical trial results information specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)) or in § 11.48, as applicable, must be submitted no later than 1 year after the primary completion date of the applicable clinical trial.

(b) *Delayed submission of results information with certification if seeking approval, licensure, or clearance of a new use*—(1) *General requirements.* If, prior to the results information submission deadline specified under paragraph (a) of this section, the responsible party submits a certification that an applicable clinical trial involves an FDA-regulated drug product (including a biological product) or device product that previously has been approved, licensed, or cleared, for which the manufacturer is the sponsor of the applicable clinical trial and for which an application or premarket notification seeking approval, licensure, or clearance of the use being studied (which is not included in the labeling of the approved, licensed, or cleared drug product (including a biological product) or device product) has been filed or will be filed within 1 year with FDA, the deadline for submitting clinical trial results information, as specified in sections 402(j)(3)(C) and 402(j)(3)(I) of the Public Health Service Act (42 U.S.C. 282(j)(3)(C) and 42 U.S.C. 282(j)(3)(I)) or § 11.48, as applicable, will be 30 calendar days after the earliest of the following events:

(i) FDA approves, licenses, or clears the drug product (including a biological product) or device product for the use studied in the applicable clinical trial;

(ii) FDA issues a letter that ends the regulatory review cycle for the application or submission but does not approve, license, or clear the drug product (including a biological product) or device product for the use studied in the applicable clinical trial; or

(iii) The application or premarket notification seeking approval, licensure, or clearance of the new use is withdrawn without resubmission for not less than 210 calendar days.

(2) *Two-year limitation.* Notwithstanding the deadlines specified in paragraph (b)(1) of this section, the responsible party must submit clinical trial results information specified in paragraph (b)(1) of this section not later than the date that is 2 years after the date that the certification was submitted, except to the extent that paragraph (d) of this section applies.