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you agree that the information and data contained in the neogov content may be incomplete or out of date, and that you shall not rely on it as the exclusive source of information for any purpose. you are solely responsible for any results obtained from using the services or neogov content. in addition, a clinical trial is an applicable clinical trial if the study has at least one facility location within the united states or one of its territories (42 cfr 11.22(b)(1)(ii)(d) and 42 cfr 11.22(b)(2)(iv)(a)). in contrast, for studies of drug product that are not required to submit registration information, a study is not an applicable clinical trial if the study is a phase 0 study or a phase i, ii, or iii study of a u.s. fda-regulated drug product. a study is an applicable clinical trial if it has at least one facility contact information that can be used for enrollment of patients at the site, or other participating facilities, in the study. the study is an applicable clinical trial if the study has at least one facility location. whether a study is an applicable clinical trial also depends on whether it is required to submit the registration information specified in 42 cfr 11. the results submission requirements for an act are specified in fdaaa section 402(j)(3)(e)(vi) . for studies that were ongoing as of december 26, 2007, if the results of the act were first published, or if the results were first disclosed in another way, no later than 1 year after the date the primary completion date (including the date the results were first published, disclosed in another way, or the results became known to the applicant or investigator), or as otherwise specified in the regulatory provisions applicable to the study, the results information must be submitted to clinicaltrials.gov, as specified in section 2.c.5. of the final rule. in addition, if the results submission deadline for the study has passed and the results are first published, or if the results are first disclosed in another way, no later than 1 year after the date the primary completion date, the results information must be submitted to clinicaltrials. for studies that are ongoing as of december 26, 2007, if the results of the act were first published, or if the results were first disclosed in another way, no later than 1 year after the date the primary completion date (including the date the results were first published, disclosed in another way, or the results became known to the applicant or investigator), or as otherwise specified in the regulatory provisions applicable to the study, the results information must be submitted to clinicaltrials. if the results submission deadline has already passed for an act affected by the federal court decision in seife et al. v. hhs et al., 18-cv-11462 (nrb) (s.d.n.y. feb. 24, 2020), what is the deadline for submitting results information for such an act

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An applicant may elect to submit either an application or a premarket notification to FDA with respect to an active, ongoing study that began after January 18, 2017, or an application or a premarket notification for which registration information was voluntarily submitted to FDA pursuant to 42 CFR 11.60(c), if the study continues to meet the definition of an active, ongoing study for which registration information must be submitted. For premarket notification purposes, and for purposes of determining the date by which any information must be submitted, a study is an ongoing study if the study has been or is expected to be terminated, for any reason, but continues or could continue to be used to support FDA's regulatory decision. For purposes of determining the date by which information must be submitted, these ongoing studies include: (a) any nonapplicable clinical trial (non-ACT) that was initiated on or before January 18, 2017, and reached its primary completion date before December 26, 2017, including any amendments of the nonapplicable clinical trial's protocol that did not receive approval of the amendment by any human subjects protection review board; (b) any pre-FDAAA applicable clinical trial (ACT) that was initiated on or before January 18, 2017, and reached its primary completion date before September 27, 2017, including any amendments of the pre-FDAAA ACT's protocol that did not receive approval of the amendment by any human subjects protection review board; and (c) any premarket notification that was voluntarily submitted to FDA pursuant to 42 CFR 11.60(c) after the submission of the nonapplicable or pre-FDAAA applicable clinical trial (including any amendments of the protocol of the nonapplicable or pre-FDAAA applicable clinical trial) that was previously submitted to FDA to describe an application or premarket notification for approval, licensure, or clearance to market a drug, biologic, or device product studied in the clinical trial. 5ec8ef588b

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