OMB#0925-0586
Exp. Date:

8/31/2015

Extension Request

Delayed Results - OPTIONAL: A responsible party may delay the deadline for submitting results information under Section 801 of the Food and Drug Administration Amendments Act if one of the two certification conditions below applies to the applicable clinical trial. Alternatively, the responsible party may request an extension of the results submission deadline for good cause. The extension must be granted by the NIH Director. To delay the results submission deadline using either of these mechanisms, all [*]-marked data elements are required, except as noted below.

Delay Results Type [*] : Select one

Certify Initial Approval - trial completed before a drug, biologic or device studied in the trial is initially approved, licensed or cleared by the FDA (for any use)

Certify New Use - the manufacturer of a drug, biologic or device is the sponsor of the trial and has filed or will file within one year, an application seeking FDA approval, licensure, or clearance of the new use (i.e., use not included in the labeling of the approved drug, biologic or device) studied in the trial

Extension - request, for good cause, an extension of the deadline for the submission of results

Note: If a manufacturer (who is the responsible party) makes a certification under "Certify New Use" the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report to the FDA for licensure, approval, or clearance of the use studied in the clinical trial. [42 U.S.C. 282 (j)(3)(E)(v)(II)]

Intervention Name(s) [*] : Required when Delay Results Type is "Certify Initial Approval" or "Certify New Use." Provide the name of one or more drugs, biological products or devices to which

the certification applies. For drugs use generic name; for other types of interventions provide a brief descriptive name. The name(s) entered should match Intervention Name(s) provided in the protocol section.
FDA Application Number(s): Provide at least one FDA application number (e.g., NDA, BLA, or PMA number), if available, when Delay Results Type is "Certify Initial Approval" or "Certify New Use."

Requested Submission Date [*] : Required when Delay Results Type is "Extension." Provide the month and year when results are expected to be submitted.

Explanation [*] : Required when Delay Results Type is "Extension." Provide a written explanation that demonstrates good cause for the extension. Provide sufficient information to allow for evaluation of the request. Note that "pending publication" is not considered "good cause" for an extension. (Limit: 999 characters)