***Pediatric Study Progress[1]***

The following table provides statistics on the progress of studies with a due date of September 27, 2007 and later. Some of these studies may be from deferrals granted prior to passage of the FDA Amendments Act (FDAAA). These statistics reflect data collected through December 31, 2024.

| | |
|---|---|
| CBER Total Number of Studies Completed by Due Date[2] | 86 |
| CBER Total Number of Studies Pending on Due Date[2] | 3 |
| CBER Total Number of Studies that have not Reached Due Date | 33 |
| CBER Total Number of Studies with a Due Date of 9/27/07 or Later | 122 |

1. In accordance with Section 505B(f)(6)(D) of the Act, as amended by FDAAA - Title IV, Pediatric Research Equity Act of 2007 (Pub. L. No. 110-85)

2. Please note that all studies deferred under PREA are considered Postmarketing Requirements (PMRs) and are assigned a specific status depending on their progress. The following points discuss how such studies were counted. For a list of PREA PMR Status definitions please scroll down.

- Any studies that were “Released” before their due date are not included in any of these statistics.

- "Number of Studies Completed by Due Date" includes studies with a PREA PMR status of either “Fulfilled” or “Submitted” status. Note: In CBER, PREA PMRs will remain in “submitted” status until a supplement is submitted and acted upon.

- "Number of Studies Pending on Due Date" includes anything that was still pending but due date has passed.

- “Number of Studies that have not Reached Due Date” anything in pending status or delayed study that has not reached the due date.

- “Number of Studies with a Due Date of 9/27/07 or Later” including the previous 3 rows.

The definition for each PMR status follows:

**Pending**: The study has not been initiated (i.e., no subjects have been enrolled nor animals dosed) but does not meet the criterion for delayed (i.e., the original projected date for initiation of patient accrual or initiation of animal dosing has not passed).

**Ongoing**: The study is proceeding according to, or is ahead of, the original schedule. The FDA considers a study to be ongoing until a final study report is submitted to the FDA, provided that the activities are proceeding according to the original study schedule. If patient accrual or animal dosing has started but is not complete, and the projected date for completion of that milestone has passed, the study should be categorized as delayed.

**Submitted**: The Applicant has concluded or terminated the study and has submitted a final study report to the FDA, but FDA has not yet notified the Applicant in writing that the study requirement has been fulfilled or that the requirement has been released. Note: CBER will not consider a PREA PMR “fulfilled” based solely on the results of a final study report. A supplement is required (see below).

**Fulfilled**: CBER will not consider an outstanding PREA PMR “fulfilled” until such time as a labeling or efficacy supplement is submitted and acted upon in order to incorporate pediatric information into the label.

**Released**: FDA has informed the Applicant that it has been released from its obligation to conduct the postmarketing study because the study is either no longer feasible or would no longer provide useful information or the study is being replaced by a new requirement.

**Delayed**: The progression of the study is behind the original study schedule. Delays can occur in any phase of the study, including patient enrollment, analysis of study results, or submission of the final study report to the FDA. While the original study schedule — not a revised schedule — serves as the basis for defining a study as delayed, each phase of the study will be considered as on its own merits. If the applicant has one delayed phase, but gets back on schedule during the next phase, the delayed status will no longer apply.

**Terminated**: The applicant ended the study before completion and has not yet submitted a final study report to the FDA.

**CBER** = Center for Biologics Evaluation & Research

For more information on postmarketing requirement and commitment studies and clinical trials that occur after a drug or biological product has been approved by FDA please visit the http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm.