

Pediatric Studies – Annual Status Summary¹

The table below provides a summary of information submitted by applicants regarding the progress they have made conducting pediatric studies, each of which follows the approval of a deferral.

These statistics are updated and posted on an annual basis and reflect the total number of pediatric studies, from CDER and CBER, organized by status and calendar year.

Study Status²	2007³	2008	2009	2010	2011	2012	2013⁵	2014	2015	2016	2017	2018
Pending	188	177	212	257	253	260	319	293	337	282	295	280
Ongoing	8	25	30	36	37	45	125	141	131	152	163	159
Submitted	16	23	33	23	21	21	17	30	17	26	31	29
Fulfilled ⁶	1	8	24	35	50	76	99	147	186	240	286	322
Released ⁶	1	8	30	43	59	108	155	196	242	284	371	429
Delayed	11	35	46	63	79	94	48	56	60	90	84	121
Terminated	1	3	3	3	3	4	3	5	4	4	3	4
Total # Products ⁴	190	230	260	267	253	342	400	343	354	365	374	372

1. In accordance with section 505B(a)(4)(C) of the Federal Food, Drug, and Cosmetic Act.

2. The definition for each status follows:

Pending: The study has not been initiated (i.e., no subjects have been enrolled or 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 as long as 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 commitment has been fulfilled or that the commitment has been released.

Fulfilled: The applicant has submitted the final study report for the commitment, and upon review of the final study report, FDA is satisfied that the applicant has met the terms of the commitment.

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.

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 in its own right. 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.

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>. Please note that this database is updated on a quarterly basis so the status of some of these studies will change throughout the year.

3. Pediatric studies that were released or fulfilled, or had a due date, prior to enactment of FDAAA (September 27, 2007) are not included in this table.

4. The total number of distinct products (original NDAs and BLAs) for which pediatric studies had one of the statuses described above. Please note that a product may be associated with more than one pediatric study and vice versa.

5. The sharp decrease in the number of delayed studies is due, in large part, to the number of deferral extensions granted under FDASIA. Many of these same studies were subsequently converted to a status of pending or ongoing.

6. The number of fulfilled and released PREA PMRs are cumulative.