Pediatric Studies – Annual Status Summary[1]

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 Status[2]	2007[4]	2008	2009	2010	2011	2012	2013[6]	2014	2015	2016	2017	2018
Ongoing[3]	196	202	242	293	290	305	444	434	468	434	458	439
Fulfilled	1	7	16	11	15	26	23	48	39	54	50	37
Released	1	7	22	13	16	49	47	41	46	42	89	59
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[5]	190	230	260	267	253	342	400	343	354	365	374	372

Study Status[2]	2019	2020	2021	2022	2023
Ongoing[3]	425	363	360	357	348
Fulfilled	54	52	57	61	61
Released	42	60	36	29	54
Delayed	144	200	219	220	250
Terminated	1	1	1	1	0
Total # Products[5]	394	398	400	377	415

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.

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. Ongoing combines all PREA PMRs with a status of pending or ongoing. Please note that this convention only applies to this annual PREA report.

4. 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.

5. 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.

6. 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.