CDER Pediatric Study Deferrals and Deferral Extensions[1]

This report provides the number of pediatric study deferrals requested,[2] the number of deferrals granted,[3] the number of deferral extensions requested, the number of deferral extensions granted, and a table detailing the granted deferrals and deferral extensions, through 12/31/20. The information in the table is presented in the order the deferrals were granted, with the most recently granted deferral listed first.

Total deferrals[4] requested: 655
Total deferrals granted: 564
Total deferral extensions[5] requested: 807
Total deferral extensions[5] granted: 534

[Use the Back button and see the CDER Deferred Pediatric Studied Granted Table (XLS)][6]

1. This report is prepared annually in response to Sections 505B(f)(6)(D)(i), 505B(f)(6)(D)(ii), and 505B(f)(6)(I) of the Food, Drug and Cosmetic Act ("FD&C Act").

2. Requests for deferrals were identified in NDAs and BLAs submitted to CDER. This number includes deferral requests contained in applications, some of which the Agency has not yet approved, or for which the Agency has determined that a deferral is not appropriate. This number does not include deferral requests for products exempt from PREA (e.g., orphan drugs).

3. Granted deferrals were identified in approval letters.

4. FDA began reporting deferral information in response to the Food and Drug Administration Amendments Act of 2007 (FDAAA), which was enacted 9/27/07.

5. Section 505B(a)(4)(B) of the FD&C Act outlines the process for deferral extensions. FDA began reporting deferral extension information in response to the Food and Drug Administration Safety and Innovation Act (FDASIA), which was enacted 07/09/12. Both of these deferral extension statistics are tracked by individual study, which includes instances of multiple requests and decisions for the same study over time.

Reasons for deferral extensions	**Examples of the types of scenarios with each reason**
Delays due to issues with the study drug and/or comparator drug.	• Delays developing an age-appropriate formulation. • Product quality and stability issues. • Comparator drug shortage.
Delays involving study participants, sites, and/or management.	• Difficulty recruiting study participants. • High rate of site personnel turnover. • Additional time needed to address unexpected issues in study conduct.
Delays due to safety and/or pharmacokinetic issues.	• Additional safety data are required. • Must review new pharmacokinetic data before proceeding with the study. • Study proceeding with a more cautious approach due to new potential safety signals.

Delays due to continuing interaction between the applicant and the FDA.	• The FDA placed the study on clinical hold. • The FDA requested a change in the protocol. • The applicant and the FDA are negotiating a different study to fulfill the PREA requirement.
Additional time required to prepare the study report and/or submission.	• Delays collecting and compiling the study data. • Additional time required to analyze the study data. • Additional time required to prepare a supplemental NDA with appropriate pediatric labeling.

6. Spreadsheet Notes:

a. The “Deferral Granted” date is the date the application is approved, since deferrals are granted within approval letters.

b. Section 505B(a)(4)(A) of the FD&C Act lists the appropriate reasons for granting deferrals.

c. Section 505B(a)(4)(B) of the FD&C Act discusses deferral extensions. Additional information about the reasons deferral extensions were granted is included in this spreadsheet:

d. Each study due date represents one pediatric post-marketing study requirement (PMR). Where deferral extensions have been granted, the original study due date is struck through, and the new study due date is listed below the original date.

e. “Study Complete” dates indicate when the FDA received studies. If upon review of a study, the FDA determines that a PREA PMR requirement was not met, this date will be removed. If the FDA releases a PMR, it is deleted from this table unless the PMR is superseded by another PMR (the Study Complete date may be revised in this circumstance); therefore, the total number of deferrals granted may be more than the number of rows in the table.

f. Any deferrals granted prior to FDAAA enactment (i.e., 09/27/07) where an extension of the deferred study due date was granted after FDASIA was enacted (i.e., 07/09/12) are also included in this spreadsheet. Prior to FDAAA, reasons for granting deferrals were not tracked.