CDER Pediatric Waivers[1]

This report provides the number of pediatric study waivers requested, the number of waivers granted, and the number of times waivers were granted for each allowable reason, through 12/31/22.[2]

Total waivers requested[3]	2101
Total waivers granted	1782
Reasons waivers were granted[4]	
Necessary Studies Impossible or Highly Impracticable	1432
Evidence Strongly Suggests Product Would be Ineffective	10
Evidence Strongly Suggests Product Would be Unsafe	118
Evidence Strongly Suggests Product Would be Ineffective and Unsafe	40
Product Does Not Represent a Meaningful Therapeutic Benefit over Existing Therapies for Pediatric Patients and Product Is Not Likely to be Used by a Substantial Number of Pediatric Patients	170
Applicant Can Demonstrate That Reasonable Attempts to Produce a Pediatric Formulation Necessary for that Age Group Have Failed	7

[Use the Back button & see the CDER Waivers of Pediatric Studies Granted Table (XLS)][5]

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

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

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

4. A waiver may be granted for more than one reason; therefore, the total number of individual reasons waivers were granted will be greater than the total number of waivers granted. Section 505B(a)(4) of the FD&C Act specifies the allowable reasons for granting waivers.

5. Table Notes:

a. The "Waiver Granted" date is generally the date the application was approved, but there were a small number of waivers that were granted outside of an approval action.

b. The age range is taken from the letter that granted the waiver.

c. Full waivers are recorded as 0 to 16 years of age unless the letter specified a different upper limit (usually 17 or 18 years of age).

d. Pre-menarcheal pertains to the period before menarche, which is the beginning of the menstrual function.