CBER Pediatric Waivers[1]

This report provides the numbers of pediatric study waivers that have been requested and granted, and the number of times waivers were granted for each allowable reason, through 12/31/17[2].

Total waivers requested[3]	**80**
Total waivers granted[4]	**75**
Reasons waivers were granted[5]	
Necessary Studies Impossible or Highly Impracticable	**34**
Evidence Strongly Suggests Product would be Ineffective	**5**
Evidence Strongly Suggests Product Would be Unsafe	**4**
Evidence Strongly Suggests Product Would be Ineffective and Unsafe	**2**
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	**30**
Applicant Can Demonstrate That Reasonable Attempts to Produce a Pediatric Formulation Necessary for that Age Group Have Failed	**0**
Total Number of Waivers Granted	**75**

[1] This report is prepared annually in response to Section 505B(f)(6)(E) of the Food, Drug and Cosmetic Act ("FD&C Act"), as amended by the Food and Drug Administration Safety and Innovation Act ("FDASIA").

[2] FDA began reporting waiver information in response to the Food and Drug Administration Amendments Act of 2007 (FDAAA), which was enacted 09/27/07.

[3] Requests for waivers were identified in NDAs and BLAs submitted to CDER and CBER. This number includes waiver requests for products that have not necessarily been approved. This number does not include waiver requests for products exempt from PREA (e.g., products reviewed under the President's Emergency Plan for AIDS Relief (PEPFAR)).

[4] Granted waivers were identified in approval letters.

[5] 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.