

21 U.S. Code § 355d

Internal committee for review of pediatric plans, assessments, deferrals, deferral extensions, and waivers

The Secretary shall establish an internal committee within the Food and Drug Administration to carry out the activities as described in sections 355a(f) and 355c(f) of this title. Such internal committee shall include employees of the Food and Drug Administration, with expertise in pediatrics (including representation from the Office of Pediatric Therapeutics), biopharmacology, statistics, chemistry, legal issues, pediatric ethics, neonatology, and the appropriate expertise pertaining to the pediatric product under review, such as expertise in child and adolescent psychiatry or pediatric rare diseases, and other individuals designated by the Secretary.

This document is only available to subscribers. Please [log in](#) or [purchase access](#).

[Purchase Login](#)