

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Commissioner

Office of the Chief Medical Officer

Office of Pediatric Therapeutics

Effective Date: May 13, 2024

1. Office of Pediatric Therapeutics (DCJD).

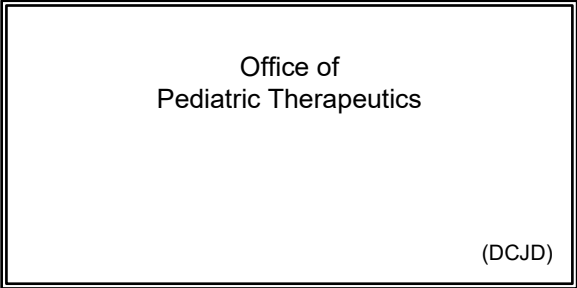
- A. Coordinates and facilitates all activities of the Food and Drug Administration (FDA) that may have any effect on the pediatric population, the practice of pediatrics, or may in any way involve pediatric issues.
- B. Coordinates the review of and communicates internally and externally pediatric adverse event reports for drugs and biologics during the 18-month period after the date of a labeling change and for pediatric Humanitarian Device Exemption (HDE) devices during the one-year period after the date of a labeling change.
- C. Provides for the review of adverse event reports and other new safety information and obtains recommendations from sources such as the Pediatric Advisory Committee (PAC) regarding whether FDA should take action. Additionally, the Office of Pediatric Therapeutics (OPT) coordinates action by the PAC for dispute resolution of pediatric safety labeling changes that are not agreed upon by the sponsor and the Commissioner not later than 90 days after referral.
- D. Coordinates with all Department of Health and Human Services (DHHS) and FDA employees who exercise responsibilities relating to pediatric therapeutics.
- E. Serves as the FDA focal point for all issues involving ethics and science with respect to the pediatric populations, including the neonatal population.
- F. Coordinates with the FDA International Programs while serving as the FDA focal point for international pediatric activities.

G. Provides pediatrics, neonatology, and bioethics expertise to the Center review divisions in the review of investigational submissions and marketing applications.

2. Authority and Effective Date.

The functional statements for the Office of Pediatric Therapeutics were approved by the Secretary of Health and Human Services on March 5, 2024 and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Office of the Chief Medical Officer
Office of Pediatric Therapeutics**



Staff Manual Guide 1113B.5
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Medical Officer, Office of Pediatric Therapeutics organization structure depicting all the organizational structures reporting to the Director: