

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND  
FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF MEDICAL PRODUCTS AND TOBACCO**

**OFFICE OF SPECIAL MEDICAL PROGRAMS**

**OFFICE OF PEDIATRIC THERAPEUTICS**

Effective Date: 07/08/2011

**1. OFFICE OF PEDIATRIC THERAPEUTICS (DKKAA)**

- A. Coordinates and facilitates all activities of the Food and Drug Administration 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, biologics and 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, 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 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
- F. Coordinates with the Office of International Programs while serving as the Agency focal point for international pediatric activities

## 2. AUTHORITY AND EFFECTIVE DATE

The functional statements for this Office were approved by the Secretary of Health and Human Services, effective July 8, 2011.

| <b>STATUS<br/>(I, R, C)</b> | <b>DATE<br/>APPROVED</b> | <b>LOCATION<br/>OF CHANGE<br/>HISTORY</b> | <b>CONTACT</b> | <b>APPROVING OFFICIAL</b>                                      |
|-----------------------------|--------------------------|---|----------------|--|
| Initial                     | 07/08/2011               | N/a                                       | OO/OM          | Secretary of the<br>Department of Health and<br>Human Services |

FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
OFFICE OF SPECIAL MEDICAL PROGRAMS  
OFFICE OF PEDIATRIC THERAPEUTICS

OFFICE OF THE DIRECTOR

STAFF MANUAL GUIDE 1141.13  
ORGANIZATIONS AND FUNCTIONS  
EFFECTIVE DATE: July 8, 2011

The following is the Food and Drug Administration, Office of Medical Products & Tobacco, Office of Special Medical Programs, Office of Pediatric Therapeutics organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF PEDIATRIC THERAPEUTICS