SMG 1141.1

FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND FUNCTIONS

FOOD AND DRUG ADMINISTRATION

OFFICE OF MEDICAL PRODUCTS AND TOBACCO

OFFICE OF SPECIAL MEDICAL PROGRAMS

Effective Date: 07/08/2011

1. OFFICE OF SPECIAL MEDICAL PROGRAMS (DKKA)

A. Serves as the agency focal point for special programs and initiatives that are cross-cutting and clinical, scientific, and/or regulatory in nature

B. Provides for the coordination of internal and external review of pediatric science, safety, ethical and international issues as mandated by law and agency activities

C. Oversees the implementation of the orphan products provisions of the Federal Food, Drug and Cosmetics Act

2. GOOD CLINICAL PRACTICE STAFF (DKKA1)

A. Provides executive leadership to the Office of Good Clinical Practice

1. Advises and assists the Commissioner, and other key officials on Good Clinical Practice (including human subject protection) issues arising in clinical trials regulated by the FDA that have an impact on policy, direction and long-range goals

2. Supports and administers FDA's Human Subject Protection (HSP)/Bioresearch Monitoring (BIMO) Council that manages and sets agency policy on Good Laboratory Practices, Bioresearch Monitoring, and Good Clinical Practices

3. Represents the Agency to other government agencies, State and local governments, industry, academia, consumer organizations, Congress, national and international organizations, and the scientific community on Good Clinical Practice policy issues

4. Provides leadership and direction on human subject protection and Good Clinical Practice matters and stimulates the application of these principles in the FDA

5. Evaluates the adequacy of Good Clinical Practice resources available to the Agency and initiates action as appropriate

6. Coordinates Agency policies related to the protection of human subjects in research, including institutional review and ethical considerations

7. Plans training programs for external use and for FDA staff on the agency's Good Clinical Practice policies

8. Coordinates and provides oversight of Good Clinical Practice policy working groups developed on the recommendation of the agency HSP/BIMO Council

9. Fosters the science of bioresearch monitoring within the Centers and the Office of Regulatory Affairs and coordinates for the Office of the Commissioner

10. Serves as the Agency coordinating point for Good Clinical Practice regulation, harmonization, and outreach activities

11. Serves as liaison between the Agency's HSP/BIMO Council and the Agency’s Management Council

12. Coordinates and assists in implementation of regulations, policies, operational initiatives, and program priorities related to clinical bioresearch monitoring as developed by the HSP/BIMO Council

13. Monitors agency activities and leads the development of a quality assurance and quality improvement program to ensure uniform application of clinical bioresearch monitoring policies across the agency

14. Serves as a liaison with other federal agencies and outside organizations, the regulated industry, and public interest groups on clinical bioresearch monitoring policy and regulatory matters

B. Oversees the functions of the Office of Combination Products as provided in Federal Food, Drug and Cosmetic Act

3. ADVISORY COMMITTEE OVERSIGHT AND MANAGEMENT STAFF (DKKA2)

Leads by working in close collaboration with all FDA Centers to provide consistent operations and seek continuous improvements in the agency advisory committee program

1. Serves as the agency liaison with the Office of the Secretary, the DHHS Committee Management Office, all of FDA's Center advisory committee support staff, and other organizations/offices within FDA

2. Ensures that all FDA committee management activities are consistent with the provisions of the Federal Advisory Committee Act, agency and departmental policies, and related guidances, regulations and statutes

4. AUTHORITY AND EFFECTIVE DATE

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

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	08/07/2009	N/a	OC/OA/OM/ OBOHCP/OMP	Secretary of the Department of Health and Human Services
Revision	07/08/2011	N/a	OO/OM	Secretary of the Department of Health and Human Services
Change	07/08/2011	N/a	OO/OM	Secretary of the Department of Health and Human Services

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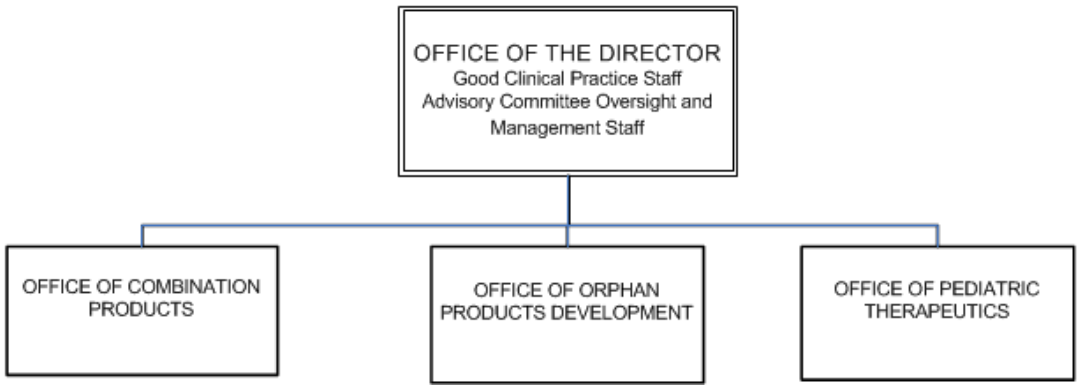

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ORGANIZATIONS AND FUNCTIONS
EFFECTIVE DATE: July 8, 2011

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

OFFICE OF SPECIAL MEDICAL PROGRAMS:

- Good Clinical Practice Staff
- Advisory Committee Oversight and Management Staff
- OFFICE OF COMBINATION PRODUCTS
- OFFICE OF ORPHAN PRODUCTS DEVELOPMENT
- OFFICE OF PEDIATRIC THERAPEUTICS