

**SMG 1261.57**

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

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF MEDICAL PRODUCTS AND TOBACCO**

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY**

**OFFICE OF MEDICATION ERROR PREVENTION AND RISK MANAGEMENT**

Effective Date: 07/08/2011

**1. OFFICE OF MEDICATION ERROR PREVENTION AND RISK  
MANAGEMENT (DKKNOG)**

- A. Directs and supports the Divisions of Medication Error Prevention and Analysis and Risk Management
- B. Leads Office of Surveillance and Epidemiology review of proposed and implemented Risk Minimization Action Plans (RiskMAPs)/Risk Evaluation and Mitigation Strategies (REMS)
- C. Coordinates risk communication components of drug safety risk management programs
- D. Coordinates reviews of proposed proprietary trade names for their potential to result in sound-alike or look-alike medication errors
- E. Performs root-cause analyses of post-marketing medication error reports

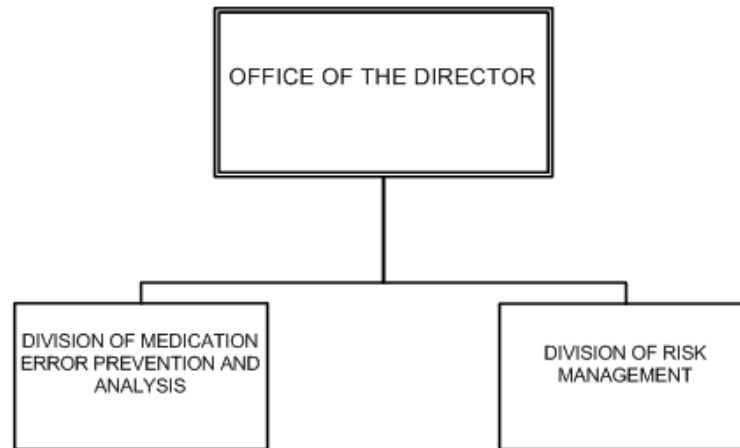
**2. AUTHORITY AND EFFECTIVE DATE**

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

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	03/03/2010	N/a	CDER/OM	Commissioner of Food and Drugs

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

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Staff Manual Guide 1261.57  
Organizations and Functions  
Effective Date: July 8, 2011

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Office of Medication Error Prevention and Risk Management organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR:

- DIVISION OF MEDICATION ERROR PREVENTION AND ANALYSIS
- DIVISION OF RISK MANAGEMENT