

SMG 1261.572

**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

DIVISION OF RISK MANAGEMENT

Effective Date: 07/08/2011

1. DIVISION OF RISK MANAGEMENT (DKKNOGB)

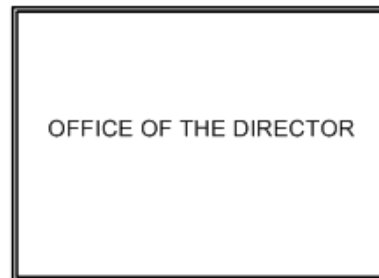
- A. Plans and directs all risk management activities in the Office of Surveillance and Epidemiology (OSE)
- B. Provides risk management expertise to OSE and the Center
- C. Reviews all proposed Risk Minimization Action Plans (RiskMAPs) or Risk Management Plans (RMPs) for conformance with the FDA standards
- D. Conducts postmarketing monitoring of all products with approved RiskMAPs
- E. Conducts evaluations of the performance of RiskMAPs
- F. In conjunction with Office of New Drugs, conducts pre-marketing risk assessments for some products
- G. Helps develop and maintain the Agency's OSE CDERNET RiskMAP Web pages and works with other Agency programs to develop and maintain RiskMAP internet pages
- H. Develops and implements internal Manuals of Policies and Procedures (MAPPs) and guidance on risk management initiatives

2. AUTHORITY AND EFFECTIVE DATE

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

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/03/2010	N/a	CDER/OM	Commissioner of Food and Drugs
Revision	07/08/2011	N/a	CDER/OM	Secretary of the Department of Health and Human Services

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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, Division of Risk Management organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR