SMG 1261.584

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 PHARMACOVIGILANCE AND EPIDEMIOLOGY

DIVISION OF PHARMACOVIGILANCE II

Effective Date: 07/08/2011

1. DIVISION OF PHARMACOVIGILANCE II (DKKNOHD)

A. Provides leadership, direction, planning, budgeting, management and supervision of Division programs and staff

B. Reviews and analyses of adverse event reports from industry submissions and from reports submitted directly to Food and Drug Administration (FDA) related to marketed drugs in order to detect safety signals and evaluate risk; and performs follow-up when such signals are detected

C. Provides development and assessment of methodologies and best practices for scientifically sound safety signal detection and drug risk evaluation related to the postmarketing safety of drugs

D. Provides safety signal detection and drug risk evaluation support to medical review Divisions in areas of responsibility, as well as, for Advisory Committee presentations

E. Provides recommendations on safety signal detection and drug risk evaluation aspects of proposed and implemented Risk Minimization Action Plans (RiskMAPs) or Risk Management Plans (RMPs)

F. Provides input on signal detection and drug risk evaluation included in information for the public related to significant safety information regarding drugs, biologics, devices and foods

G. Develops and implements internal Manuals of Policies and Procedures (MAPPs) and guidance on safety signal detection and drug risk evaluation 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, effective July 8, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/03/21011	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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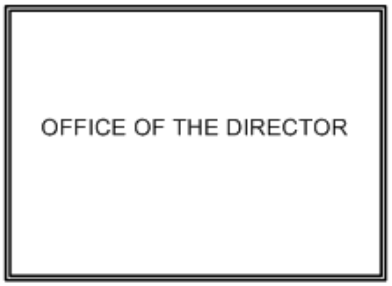

Staff Manual Guide 1261.584
Organizations and Functions
Effective Date: July 8, 2011

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 Pharmacovigilance and Epidemiology, Division of Pharmacovigilance II organization structure depicting all the organizational structures reporting to the Director.

OFFICE OF THE DIRECTOR