SMG 1410.110

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS

ISSUANCE OF WRITTEN NOTICES CONCERNING PATENT INFORMATION, CURRENT GOOD MANUFACTURING PRACTICES AND FALSE OR MISLEADING LABELING OF NEW DRUGS

Effective Date: 04/10/2009

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under Sec. 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) regarding the issuance of written notices:

1. The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), the Directors, Office of New Drugs and Office of Pharmaceutical Science, and the Associate Director for Medical Policy, CDER.

2. The Director and Deputy Director, Office of Compliance, CDER.

3. The Director and Deputy Director, Division of Scientific Investigations, Office of Compliance, CDER.

4. The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

5. The Director and Deputy Director, Division of Compliance Risk Management and Surveillance, Office of Compliance, CDER.

6. The Director and Deputy Director, Division of New Drug Labeling Compliance, Office of Compliance, CDER.

7. The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), the Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER, and the Directors, Division of Case Management, Division of Inspections and Surveillance, and Division of Manufacturing and Product Quality, OCBQ, CBER.

8. The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), Director and Deputy Directors of the Office of Device Evaluation, and the Director and Deputy Director Office of In Vitro Diagnostic Devices Evaluation and Safety, CDRH.

9. Regional Food and Drug Directors.

10. District Directors.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation on April 10, 2009.