SMG 1410.108

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS

EXTENSIONS OR STAYS OF EFFECTIVE DATES FOR COMPLIANCE WITH CERTAIN LABELING REQUIREMENTS FOR HUMAN PRESCRIPTION DRUGS

Effective Date: 04/10/2009

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The following officials are authorized to extend or stay an effective date in 21 CFR, Part 200, section 201.59 for compliance with certain labeling requirements for human prescription drugs.

1. For drugs assigned to their organizations:

    a. The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

    b. The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Cellular, Tissue and Gene Therapies (OCTGT), CBER.

    c. The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OCTGT, CBER.

2. For drugs assigned to their organizations:

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

    b. The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, Office of Antimicrobial Products (OAP), Office of Nonprescription Products (ONP) and Office of Oncology Drug Products (OODP), Office of New Drugs, CDER.

    c. The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, Office of Antimicrobial Products (OAP), Office of Nonprescription Products (ONP) and Office of Oncology Drug Products (OODP), Office of New Drugs, CDER.

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.