FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - HUMAN DRUGS

ISSUANCE OF NOTICES IMPLEMENTING THE PROVISIONS OF THE DRUG AMENDMENTS OF 1962

Effective Date: 04/14/2003

1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

The Director, the Deputy Director, and the Directors, Office of New Drugs and Office of Pharmaceutical Science, Center for Drug Evaluation and Research; and the Director, the Deputy Director, and the Director and Deputy Directors, Office of Device Evaluation, Center for Devices and Radiological Health, are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87-781) by announcing new or revised efficacy findings on human drugs that are or were subject to the provisions of section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

This delegation was approved on April 14, 2003.