**SMG 1410.106**

# FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

## REGULATORY - HUMAN DRUGS

## ISSUANCE OF NOTICES RELATING TO PROPOSALS TO REFUSE APPROVAL OR TO WITHDRAW APPROVAL OF NEW DRUG APPLICATIONS AND THEIR SUPPLEMENTS

Effective Date: 06/21/2012

### 1. AUTHORITIES DELEGATED AND TO WHOM DELEGATED.

A. Except for those drugs listed in 21 CFR, Part 314, Section 314.440(b), the following officials are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under Section 505 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355) and Part 314 of 21 CFR and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

1. The Director and the Deputy Directors, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco (OMPT)

2. The Directors, Office of New Drugs and Office of Pharmaceutical Science, CDER, OMPT

B. For those drugs listed in 21 CFR, Part 314, Section 314.440(b), the following officials are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under Section 505 of the Act and Part 314 of 21 CFR and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

1. The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), OMPT

### 2. REDELEGATION

These officials may not further redelegate this authority.

## 3. EFFECTIVE DATE

The Commissioner of Food and Drugs approved this delegation, via memorandum, on June 21, 2012.

| STATUS (I, R, C) | DATE APPROVED | LOCATION OF CHANGE HISTORY | CONTACT | APPROVING OFFICIAL |
|---|---|---|---|---|
| Initial | 04/29/2009 | N/a | CDER/OM | Commissioner of Food and Drugs |
| Revision | 06/21/2012 | N/a | OO/OBS | Commissioner of Food and Drugs |