

SMG 1410.203

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - BIOLOGICS

ISSUANCE OF NOTICES OF OPPORTUNITY FOR A HEARING ON PROPOSALS FOR DENIAL OF APPROVAL OF APPLICATIONS FOR LICENSES, SUSPENSION OF LICENSES, OR REVOCATION OF LICENSES AND CERTAIN NOTICES OF REVOCATION OF LICENSES

Effective Date: 06/27/2003

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The Director and Deputy Directors, Center for Biologics Evaluation and Research, and the Director and Deputy Director, CDER are authorized to issue:

1. Notices of opportunity for a hearing on proposals to deny approval or filing of applications for biologics licenses under 21 CFR, Part 600, section 601.4(b) of this chapter.
2. Notices of opportunity for a hearing on proposals to revoke biologics licenses under section 601.5(b).
3. Notices of revocation, at the manufacturer's request, of biologics licenses under sections 601.5(a) and 601.8.
4. Notices of revocation when the manufacturer has waived the opportunity for hearing under section 601.7(a).
5. Notice of biologics license suspensions under Sec. 601.6.

2. REDELEGATION.

These officials may not further redelegate these authorities.

3. EFFECTIVE DATE.

This delegation was signed by the Commissioner on June 27, 2003.