SMG 1410.204

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - BIOLOGICS

ISSUANCE AND REVOCATION OF LICENSES FOR THE PROPAGATION OR MANUFACTURE AND PREPARATION OF BIOLOGICAL PRODUCTS

Effective Date: June 8, 2010

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The following officials are authorized to issue licenses under section 351 of the PHS Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the PHS Act, to revoke such licenses at the manufacturer's request, and take additional actions and impose additional requirements after licensing:

1. The Director, Deputy Directors and the Associate Director for Review Management, Center for Biologics Evaluation and Research (CBER)

2. Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Cellular, Tissue and Gene Therapies, and Office of Compliance and Biologics Quality, CBER

3. The Director and Deputy Director, Center for Drug Evaluation and Research (CDER)

4. The Director and Deputy Director, Office of New Drugs, CDER

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

This delegation was signed by the Commissioner, via memorandum, on June 8, 2010.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/08/2010	N/a	CBER	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs