

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY – BIOLOGICS

**NOTIFICATION OF RELEASE FOR DISTRIBUTION
OF BIOLOGICAL PRODUCTS**

Effective Date: January 5, 2011

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The following officials are authorized to issue written notices of release for distribution of licensed biological products under 21 CFR subchapter F (parts 600 through 680.3):

- A. The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).
- B. The Director and Deputy Director, Office of Compliance and Biologics Quality (OCBQ), CBER.
- C. The Director and Deputy Director, Division of Manufacturing and Product Quality (DMPQ), OCBQ, CBER.
- D. Chief, Product Release Branch, DMPQ, CBER.
- E. The Director and Deputy Directors, CDER.
- F. The Director and Deputy Director, Office of Compliance, CDER.

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 January 5, 2011.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/02/2010	N/a	OC/OA/ OM/OMP	Commissioner of Food and Drugs