

**FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF
AUTHORITY**

REGULATORY – HUMAN DRUGS

**TERMINATIONS OF ILLEGITIMATE AND HIGH RISK OF ILLEGITIMACY
PRODUCT NOTIFICATIONS PERTAINING TO THE DRUG SUPPLY CHAIN
SECURITY ACT**

Effective Date: March 29, 2016

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to perform all termination of notification functions of the Commissioner of Food and Drugs under Sections 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the Federal, Food, Drug & Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv)):

1. Director and Deputy Directors, Center for Drug Evaluation and Research (CDER), Office of Medical Products and Tobacco (OMPT).
2. Director and Deputy Directors, Office of Compliance (OC), CDER, OMPT.
3. Director and Deputy Director, Office of Drug Security, Integrity, and Response (ODSIR), OC, CDER, OMPT.
4. Director and Deputy Director, Division of Supply Chain Integrity (DSCI), ODSIR, OC, CDER, OMPT.
5. Branch Chief, Supply Chain Response and Enforcement Branch (SCREB), DSCI, ODSIR, OC, CDER, OMPT.
6. Branch Chief, Supply Chain Strategy and Policy Branch (SCSPB), DSCI, ODSIR, OC, CDER, OMPT.
7. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), OMPT.
8. Director and Deputy Director, Office of Compliance and Biologics Quality (OCBQ), CBER, OMPT.
9. Director, Division of Case Management (DCM), OCBQ, CBER, OMPT.

10. Branch Chief, Biological Drug and Device Compliance Branch (BDDCB), DCM, OCBQ, CBER, OMPT.

2. REDELEGATION.

These officials may not further re-delegate this authority.

3. EFFECTIVE DATE.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on March 29, 2016.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	03/29/2016	N/a	CBER/OCBQDCM/BDDCB and CDER/OC/ODSIR/DSCI/SCSPB	Robert M. Califf, M.D., Commissioner of Food and Drugs