SMG 1410.37

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – GENERAL REDELEGATIONS OF AUTHORITY

ISSUANCE OF ORDERS AND DECISIONS RELATING TO MATTERS UNDER 21 CFR 10.75 IN THE OFFICE OF THE COMMISSIONER

Effective Date: April 15, 2016

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following official is authorized to issue responses to requests for review under 21 CFR 10.75(c) on behalf of the Commissioner, and make all findings and decisions required for such responses, whenever the decision being challenged was made by staff within the Office of Special Medical Programs, including staff within the Office of Good Clinical Practice, the Office of Combination Products, the Office of Orphan Products Development, and the Office of Pediatric Therapeutics, unless those decisions involve directly evaluating the safety and effectiveness of a medical product:

1. Associate Commissioner for Special Medical Products, Office of Special Medical Products (OSMP), Office of Medical Products and Tobacco (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 April 15, 2016.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	04/15/2016	N/a	OC/OCS/ OSI	Robert M. Califf, M.D. Commissioner of Food and Drugs