

SMG 1410.803

FDA STAFF MANUAL GUIDES, VOLUME II - DELEGATIONS OF AUTHORITY

REGULATORY - IMPORTS AND EXPORTS

MANUFACTURER'S RESIDENT IMPORT AGENTS

Effective Date: 01/05/2010

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to reject manufacturer's designation of import agents under Title 21, Code of Federal Regulations, Part 1000, section 1005.25(b).

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, 2010.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/05/2010	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs