**SMG 1410.803**

**FDA Staff Manual Guides, Volume II – Delegations of Authority**

**Regulatory – Imports and Exports**

**Reject Manufacturer's Designation of Import Agents**

Effective Date: 11 June 2024

## 1. Authority Delegated and To Whom Delegated.

A. The officials listed below are authorized under 21 CFR 1005.25(b) to reject manufacturer's designation of import agents:

(1) Center for Devices and Radiological Health (CDRH) Director and Deputy Directors.

(2) CDRH/Office of Product Evaluation and Quality (OPEQ) Director; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.

(3) CDRH/OPEQ/Office of Regulatory Programs (ORP) Director.

## 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 11 June 2024.

| Status | Date Approved | Location of Change History | Contact | Approving Official |
|---|---|---|---|---|
| Initial | 04/142003 | N/A | OC/ OA/ OM/OMP | Lester Mills Crawford, D.V.M., Ph.D. Acting Commissioner of Food and Drugs |
| Revision | 01/05/2010 | N/A | CDRH/ OMO/ DEMO | Margaret A. Hamburg, M.D. Commissioner of Food and Drugs |
| Revision | 06/11/2024 | N/A | CDRH/ OM | Robert M. Califf, M.D., MACC Commissioner of Food and Drugs |