

**SMG 1410.605**

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

**REGULATORY - RADIATION CONTROL**

**MANUFACTURERS REQUIREMENT TO PROVIDE DATA TO ULTIMATE  
PURCHASERS OF ELECTRONIC PRODUCTS**

Effective Date: July 05, 2013

**1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.**

The Director and Deputy Directors, Center for Devices and Radiological Health, Office of Medical Products and Tobacco, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under Section 537(c) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360nn(c)).

- A. Director and Deputy Directors, Center for Devices and Radiological Health, Office of Medical Products and Tobacco (OMPT).
- B. Director and Deputy Directors, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, OMPT.

**2. REDELEGATION.**

These officials may not further redelegate these authorities.

**3. EFFECTIVE DATE.**

The Commissioner of Food and Drugs approved this delegation, via memorandum, on July 5, 2013.

<b>STATUS (I, R, C)</b>	<b>DATE APPROVED</b>	<b>LOCATION OF CHANGE HISTORY</b>	<b>CONTACT</b>	<b>APPROVING OFFICIAL</b>
Initial	01/05/2010	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs
Revision	07/05/2013	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D., Commissioner of Food and Drugs