

**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: 6 February 2023

**1. Authority Delegated and To Whom Delegated.**

A. The officials listed below, for products assigned to their respective organizations, 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)):

- (1) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (2) CDRH/Office of Product Evaluation and Quality (OPEQ) Director and Deputy Directors.
- (3) CDRH/OPEQ/Clinical and Scientific Policy Staff (CSPS) Chief Medical and Science Officer.
- (4) CDRH/OPEQ/Compliance and Quality Staff (CQS) Associate Director for Compliance and Quality.
- (5) CDRH/OPEQ/Regulation, Policy, and Guidance Staff (RPGS) Deputy Director for Regulatory Policy.
- (6) CDRH/OPEQ/Office of Health Technology VIII (OHT VIII) Director, Deputy Directors, Associate Directors, Chief Medical Officers, Division Directors and Assistant Division Directors.

**2. Redelelegation.**

These officials may not further redelegate this authority.

**3. Effective Date.**

The Commissioner of Food and Drugs approved this delegation, via memorandum, on 6 February 2023.

<b>Status</b>	<b>Date Approved</b>	<b>Location of Change History</b>	<b>Contact</b>	<b>Approving Official</b>
Initial	04/14/2003	N/A	OC/ OA OM/OMP	Mark Barr McClellan, M.D., Ph.D. Commissioner of Food and Drugs
Revision	01/05/2010	N/A	OC/ OA/ OM/OMP	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	07/05/2013	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	02/06/2023	N/A	CDRH/ OMO/ DWM	Robert M. Califf, M.D., MAcc Commissioner of Food and Drugs