SMG 1410.410

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Determinations that Medical Devices Present Unreasonable Risk of Substantial Harm

Effective Date: 4 March 2022

1. Authority Delegated and to Whom Delegated.

A. The officials listed below, for medical devices assigned to their respective organizations, are authorized under section 518(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(a)) to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof:

(1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Director.

(2) CBER/Office of Compliance and Biologics Quality (OCBQ) Director and Deputy Directors.

(3) Center for Drug Evaluation and Research (CDER) Director and Deputy Directors.

(4) CDER/Office of Compliance (OC) Director and Deputy Directors.

(5) CDER/Office of Generic Drugs (OGD) Director and Deputy Directors.

(6) CDER/Office of New Drugs (OND) Director and Deputy Directors.

(7) CDER/Office of Pharmaceutical Quality (OPQ) Director and Deputy Directors.

(8) Center for Devices and Radiological Health (CDRH) Director, Deputy Center Director for Science, and Deputy Center Director for Policy.

(9) CDRH/Office of Product Evaluation and Quality (OPEQ) Director and Deputy Directors.

(10) CDRH/OPEQ/Clinical and Scientific Policy Staff (CSPS) Chief Medical and Science Officer.

(11) CDRH/OPEQ/Regulation, Policy, and Guidance Staff (RPGS) Deputy Director for Regulatory Policy.

(12) CDRH/OPEQ/Office of Health Technology I (OHT I) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(13) CDRH/OPEQ/Office of Health Technology II (OHT II) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(14) CDRH/OPEQ/Office of Health Technology III (OHT III) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(15) CDRH/OPEQ/Office of Health Technology IV (OHT IV) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(16) CDRH/OPEQ/Office of Health Technology V (OHT V) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(17) CDRH/OPEQ/Office of Health Technology VI (OHT VI) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(18) CDRH/OPEQ/Office of Health Technology VII (OHT VII) Director, Deputy Directors, Associate Director for Strategic Initiatives, and Chief Medical Officers.

(19) CDRH/OPEQ/Office of Health Technology VIII (OHT VIII) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

(20) CDRH/OPEQ/Office of Regulatory Programs (ORP) Director, Deputy Directors, Associate Director, and Chief Medical Officer.

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 4 March 2022.

Status	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/23/2009	N/A	OC/ OA/ OM/OMP	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	03/23/2011	N/A	CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	07/14/2014	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	06/23/2015	N/A	OMPT/ CDRH/ OMO/ DWM	Stephen M. Ostroff, M.D. Acting Commissioner of Food and Drugs

Status	Date Approved	Location of Change History	Contact	Approving Official
Revision	03/04/2022	N/A	CDRH/ OMO/ DWM	Robert M. Califf, M.D., MAcc Commissioner of Food and Drugs