SMG 1410.405

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

Notification to Petitioners of Determinations Made on Petitions for Reclassification of Medical Devices

Effective Date: 14 May 2024

1. Authority Delegated and To Whom Delegated.

A. The officials listed below, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in Class III (premarket approval) by sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360c(f) and 360j(l)) and denials of petitions for reclassification of medical devices that are submitted under section 513(e) of the Act (21 U.S.C. 360c(e)) (except for petitions submitted in response to Federal Register notices initiating standard-setting under section 514(b) of the Act (21 U.S.C. 360d(b)) or premarket approval under section 515(b) of the Act (21 U.S.C. 360e(b)):

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

(2) CBER/Office of Blood Research and Review (OBRR) Director and Deputy Directors.

(3) CBER/Office of Tissues and Advanced Therapies (OTAT) Director and Deputy Directors.

(4) CBER/Office of Vaccines Research and Review (OVRR) Director and Deputy Directors.

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

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

(7) Center for Devices and Radiological Health (CDRH) Director and Deputy Center Director for Science.

(8) CDRH/Office of Policy (OP) Deputy Center Director for Policy, Deputy Director, and Associate Directors.

(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 14 May 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	02/24/2011	N/A	CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs

Status	Date Approved	Location of Change History	Contact	Approving Official
Revision	07/03/2014	N/A	OMPT/ CDRH/ OMO/ DEMO	Margaret A. Hamberg, M.D. Commissioner of Food and Drugs
Revision	05/14/2024	N/A	CDRH/ OM/ DWM	Robert M. Califf, M.D., MACC Commissioner of Food and Drugs