

FDA Staff Manual Guides, Volume II – Delegations of Authority

Regulatory – Medical Devices and Radiological Health

**Certain Orders Issued Pursuant to Sections 518(b) and 518(c)
of the Federal Food, Drug, and Cosmetic Act**

Effective Date: 22 April 2022

1. Authority Delegated and To Whom Delegated.

- A. The officials listed below, for medical devices assigned to their respective organizations, are authorized to perform all of the functions under Sections 518(b) and 518(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)), delegated to the Commissioner of Food and Drugs:
- (1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Directors.
 - (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; Deputy Directors; Associate Director for Compliance and Quality; Associate Director for Regulation, Policy, and Guidance; and Chief Medical & Science Officer.
 - (10) CDRH/OPEQ/Clinical and Scientific Policy Staff (CSPS) Chief Medical & Science Officer.
 - (11) CDRH/OPEQ/Compliance and Quality Staff (CQS) Associate Director for Compliance and Quality.
 - (12) CDRH/OPEQ/Regulation, Policy, and Guidance Staff (RPGS) Deputy Director for Regulatory Policy.

- (13) CDRH/OPEQ/Office of Health Technology I (OHT I) Director, Deputy Directors, Associate Director, and Chief Medical Officer.
- (14) CDRH/OPEQ/Office of Health Technology II (OHT II) Director, Deputy Directors, Associate Director, and Chief Medical Officer.
- (15) CDRH/OPEQ/Office of Health Technology III (OHT III) Director, Deputy Directors, Associate Director, and Chief Medical Officer.
- (16) CDRH/OPEQ/Office of Health Technology IV (OHT IV) Director, Deputy Directors, Associate Director, and Chief Medical Officer.
- (17) CDRH/OPEQ/Office of Health Technology V (OHT V) Director, Deputy Directors, Associate Director, and Chief Medical Officer.
- (18) CDRH/OPEQ/Office of Health Technology VI (OHT VI) Director, Deputy Directors, Associate Director, and Chief Medical Officer.
- (19) CDRH/OPEQ/Office of Health Technology VII (OHT VII), Director, Deputy Directors, Associate Director for Strategic Initiatives, and Chief Medical Officers.
- (20) CDRH/OPEQ/Office of Health Technology VIII (OHT VIII) Director, Deputy Directors, Associate Director, and Chief Medical Officer.
- (21) CDRH/OPEQ/Office of Regulatory Programs (ORP) Director, Deputy Directors, and Chief Medical Officer.
- (22) CDRH/OPEQ/ORP/Division of Regulatory Programs 1 (DRP1) Division Director and Deputy Division Director.

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 22 April 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

Status	Date Approved	Location of Change History	Contact	Approving Official
Revision	07/17/2014	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/ DEMO	Stephen M. Ostroff, M.D. Acting Commissioner of Food and Drugs
Revision	04/22/2022	N/A	CDRH/ OMO/ DWM	Robert M. Califf, M.D., MAcc Commissioner of Food and Drugs