

**FDA Staff Manual Guides, Volume II – Delegations of Authority**

**Regulatory – Medical Devices and Radiological Health**

**Investigational Device Exemptions**

Effective Date: 2 December 2022

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

- A. The officials listed below, for medical products assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360j(g)):
- (1) Center for Biologics Evaluation and Research (CBER) Director and Deputy Director.
  - (2) CBER/Office of Blood Research and Review (OBRR) Director and Deputy Director.
  - (3) CBER/Office of Tissues and Advanced Therapies (OTAT) Director, Deputy Director, and Associate Director for Regulatory Management.
  - (4) CBER/Office of Vaccines Research and Review (OVR) Director and Deputy Director.
  - (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, Deputy Center Director for Science, and Deputy Center Director for Policy.
  - (8) CDRH/Office of Product Evaluation and Quality (OPEQ) Director and Deputy Directors.
  - (9) CDRH/OPEQ/Clinical and Scientific Policy Staff (CSPS) Chief Medical & Science Officer.
  - (10) CDRH/OPEQ/Regulation, Policy, and Guidance Staff (RPGS) Deputy Director for Regulatory Policy.
  - (11) CDRH/OPEQ/Office of Clinical Evidence and Analysis (OCEA) Director, Deputy Directors, Associate Director, and Chief Medical Officer.
  - (12) CDRH/OPEQ/OCEA/Division of Clinical Evidence and Analysis 1 (DCEA1) Division Director, Deputy Division Directors, Associate Division Directors, and Assistant Division Directors.
  - (13) CDRH/OPEQ/Office of Health Technology I (OHT I) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.

- (14) CDRH/OPEQ/Office of Health Technology II (OHT II) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (15) CDRH/OPEQ/Office of Health Technology III (OHT III) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (16) CDRH/OPEQ/Office of Health Technology IV (OHT IV) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (17) CDRH/OPEQ/Office of Health Technology V (OHT V) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (18) CDRH/OPEQ/Office of Health Technology VI (OHT VI) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (19) CDRH/OPEQ/Office of Health Technology VII (OHT VII) Director, Deputy Directors, Associate Director for Medical Affairs, Chief Medical Officer, Division Directors, Deputy Division Directors, and Branch Chiefs.
- (20) CDRH/OPEQ/Office of Health Technology VIII (OHT VIII) Director, Deputy Directors, Associate Director, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (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) Director, and Deputy Directors.

B. The officials listed below, for medical products assigned to their respective organization, are authorized to enter into written agreements concerning investigational device exemption protocols under section 520(g)(7) of the Act (21 U.S.C. 360j(g)(7)):

- (1) CBER Director and Deputy Director.
- (2) CBER/OBRR Director and Deputy Director.
- (3) CBER/OTAT Director, Deputy Director, and Associate Director for Regulatory Management.
- (4) CBER/OVRR Director and Deputy Director.
- (5) CDER Director and Deputy Directors.
- (6) CDER/OND Director and Deputy Director.
- (7) CDRH Director, Deputy Center Director for Science, and Deputy Center Director for Policy.
- (8) CDRH/OPEQ Director and Deputy Directors.
- (9) CDRH/OPEQ/CSPS Chief Medical and Science Officer.

- (10) CDRH/OPEQ/RPGS Deputy Director for Regulatory Policy.
- (11) CDRH/OPEQ/OCEA Director, Deputy Directors, Associate Directors, and Chief Medical Officer.
- (12) CDRH/OPEQ/OCEA/DCEA1 Division Director, Deputy Division Directors, Associate Division Directors, and Assistant Division Directors.
- (13) CDRH/OPEQ/OHT I Director, Deputy Directors, Associate Directors, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (14) CDRH/OPEQ/OHT II Director, Deputy Directors, Associate Directors, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (15) CDRH/OPEQ/OHT III Director, Deputy Directors, Associate Directors, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (16) CDRH/OPEQ/OHT IV Director, Deputy Directors, Associate Directors, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (17) CDRH/OPEQ/OHT V Director, Deputy Directors, Associate Directors, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (18) CDRH/OPEQ/OHT VI Director, Deputy Directors, Associate Directors, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (19) CDRH/OPEQ/OHT VII Director, Deputy Directors, Associate Director for Medical Affairs, Chief Medical Officer, Division Directors, Deputy Division Directors, and Branch Chiefs.
- (20) CDRH/OPEQ/OHT VIII Director, Deputy Directors, Associate Directors, Chief Medical Officer, Division Directors, and Assistant Division Directors.
- (21) CDRH/OPEQ/ORP Director, Deputy Directors, and Chief Medical Officer.
- (22) CDRH/OPEQ/ORP/DRP1 Director and Deputy 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 2 December 2022.

| Status   | Date Approved | Location of Change History | Contact               | Approving Official   |
|----------|---------------|----------------------------|-----------------------|--|
| Initial  | 06/23/2009    | N/A                        | OC/<br>OA/<br>OM/OMP  | Margaret A. Hamberg, M.D.<br>Commissioner<br>of Food and Drugs |
| Revision | 04/01/2011    | N/A                        | CDRH/<br>OMO/<br>DEMO | Margaret A. Hamberg, M.D.<br>Commissioner<br>of Food and Drugs |

| <b>Status</b> | <b>Date Approved</b> | <b>Location of Change History</b> | <b>Contact</b>                 | <b>Approving Official</b>   |
|---------------|----------------------|-----------------------------------|--------------------------------|---|
| Revision      | 07/17/2014           | N/A                               | OMPT/<br>CDRH/<br>OMO/<br>DEMO | Margaret A. Hamberg, M.D.<br>Commissioner<br>of Food and Drugs    |
| Revision      | 11/13/2018           | N/A                               | OMPT/<br>CDRH/<br>OMO/<br>DEMO | Scott Gottlieb, M.D.<br>Commissioner<br>of Food and Drugs         |
| Revision      | 12/02/2022           | N/A                               | CDRH/<br>OM/<br>DWM            | Robert M. Califf, M.D., MAcc<br>Commissioner<br>of Food and Drugs |