SMG 1410.408

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – MEDICAL DEVICES AND RADIOLOGICAL HEALTH

APPROVAL, DISAPPROVAL, OR WITHDRAWAL OF APPROVAL OF PRODUCT DEVELOPMENT PROTOCOLS AND APPLICATIONS FOR PREMARKET APPROVAL, AND HUMANITARIAN EXEMPTIONS, FOR MEDICAL DEVICES

Effective Date: November 13, 2018

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The officials listed below, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices submitted under Section 515(f) of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 360e(f)):

1. Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), Office of Medical Products and Tobacco (OMPT).

2. Director and Deputy Director, Office of Blood Research and Review (OBRR), CBER, OMPT.

3. Director and Deputy Director, Office of Tissues and Advanced Therapies (OTAT), CBER, OMPT.

4. Director and Deputy Director, Office of Vaccines Research and Review (OVRR), CBER, OMPT.

5. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), OMPT.

6. Director, Deputy Directors, and Associate Directors, Office of Compliance (OC), CDRH, OMPT.

7. Division Directors, Deputy Division Directors, and Associate Division Directors, OC, CDRH, OMPT.

8. Director, Deputy Directors and Associate Directors, Office of Device Evaluation (ODE), CDRH, OMPT.

9. Division Directors, Deputy Division Directors, and Associate Division Directors, ODE, CDRH, OMPT.

10. Director, Program Operations Staff (POS), ODE, CDRH, OMPT.

11. Director, Deputy Directors, and Associate Directors, Office of In Vitro Diagnostics and Radiological Health (OIR), CDRH, OMPT.

12. Division Directors, Deputy Division Directors, and Associate Division Directors, OIR, CDRH, OMPT.

13. Director, Deputy Directors, and Associate Directors, Office of Surveillance and Biometrics (OSB), CDRH, OMPT.

14. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.

B. The officials listed below, for medical devices assigned to their respective organization, are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under Sections 515 and 520(l) of the Act (21 U.S.C. 360e and 360j(l)):

1. Director and Deputy Director, CBER, OMPT.

2. Director and Deputy Director, OBRR, CBER, OMPT.

3. Director and Deputy Director, OTAT, CBER, OMPT.

4. Director and Deputy Director, OVRR, CBER, OMPT.

5. Director and Deputy Directors, CDRH, OMPT.

6. Director and Deputy Directors, OC, CDRH, OMPT.

7. Division Directors, OC, CDRH, OMPT.

8. Director and Deputy Directors, ODE, CDRH, OMPT.

9. Division Directors, ODE, CDRH, OMPT.

10. Director, POS, ODE, CDRH, OMPT.

11. Director and Deputy Directors, OIR, CDRH.

12. Division Directors, OIR, CDRH, OMPT.

13. Director and Deputy Directors, OSB, CDRH, OMPT.

14. Division Directors, OSB, CDRH, OMPT.

C. The officials listed below, for medical devices assigned to their respective organization, are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications. Approval, disapproval, and withdrawn approval decisions do not apply to 30-day notice supplements. These officials also have authority to issue decisions on 30-day notice supplements. This authority may be further redelegated when a 135-day supplement is not needed:

1. Director and Deputy Director, CBER, OMPT.

2. Director and Deputy Director, OBRR, CBER, OMPT.

3. Director and Deputy Director, OTAT, CBER, OMPT.

4. Director and Deputy Director, OVRR, CBER, OMPT.

5. Director and Deputy Director, CDRH, OMPT.

6. Director and Deputy Directors, OC, CDRH, OMPT.

7. Division Directors, OC, CDRH, OMPT.

8. Director and Deputy Directors, ODE, CDRH, OMPT.

9. Division Directors, ODE, CDRH, OMPT.

10. Director POS, ODE, CDRH, OMPT.

11. Chief, Premarket Approval Section (PMA), POS, ODE, CDRH, OMPT.

12. Director and Deputy Directors, OIR, CDRH, OMPT.

13. Division Directors, OIR, CDRH, OMPT.

14. Director and Deputy Directors, OSB, CDRH, OMPT.

15. Division Directors, OSB, CDRH, OMPT.

D. The officials listed below, for medical devices assigned to their respective organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under Sections 515(d), (e), and (g) and 520(h)(1) of the Act (21 U.S.C. 360e(d), (e), and (g) and 360j(h)(1)):

1. Director and Deputy Director, CBER, OMPT.

2. Director and Deputy Director, OBRR, CBER, OMPT.

3. Director and Deputy Director, OTAT, CBER, OMPT.

4. Director and Deputy Director, OVRR, CBER, OMPT.

5. Director and Deputy Directors, CDRH, OMPT.

E. The officials listed below, for medical devices assigned to their respective organization, are authorized to approve, disapprove, or withdraw approval of applications for humanitarian device exemption (HDE) use devices for medical devices submitted under Section 520(m) of the Act (21 U.S.C. 360j(m)):

1. Director and Deputy Directors, CDRH, OMPT.

2. Director and Deputy Directors, OC, CDRH, OMPT.

3. Division Directors, OC, CDRH, OMPT.

4. Director and Deputy Directors, ODE, CDRH, OMPT.

5. Division Directors, ODE, CDRH, OMPT.

6. Director, POS, ODE, CDRH, OMPT.

7. Director and Deputy Directors, OIR, CDRH, OMPT.

8. Division Directors, OIR, CDRH, OMPT.

9. Director, Deputy Directors, and Associate Directors, OSB, CDRH, OMPT.

10. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.

F. The officials listed below, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of supplemental HDE applications:

1. Director and Deputy Directors, CDRH, OMPT.

2. Director and Deputy Directors, OC, CDRH, OMPT.

3. Division Directors, OC, CDRH, OMPT.

4. Director and Deputy Directors, ODE, CDRH, OMPT.

5. Division Directors, ODE, CDRH, OMPT.

6. Director, POS, ODE, CDRH, OMPT.

7. Chief, PMA, POS, ODE, CDRH, OMPT.

8. Director and Deputy Directors, OIR, CDRH, OMPT.

9. Division Directors, OIR, CDRH, OMPT.

10. Director, Deputy Directors, and Associate Directors, OSB, CDRH, OMPT.

11. Division Directors, Deputy Division Directors, and Associate Division Directors, OSB, CDRH, OMPT.

2. REDELEGATION.

A. The officials listed in Sections 1.A., B., D., E., and F. may not further redelegate the authorities in those sections.

B. The officials listed in Section 1.C., may further redelegate the authority for 30-day notice decisions when a 135-day supplement is not needed. This authority may be redelegated by the listed officials to positions within their respective organization down to branch chief level on a case-by-case basis.

3. EFFECTIVE DATE.

The delegations become effective upon date of signature.

The Commissioner of Food and Drugs approved this Delegation, via memorandum, on November 13, 2018.

STATUS	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/23/2009	N/a	OC/OO/OM/OMP	Commissioner of Food and Drugs
Revision	03/23/2011	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	07/14/2014	N/a	CDRH/OMO/ DEMO/AMB	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	11/13/2018	N/a	OMPT/CDRH /OM/DWM	Scott Gottlieb, M.D. Commissioner of Food and Drug

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