SMG 1410.418

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – MEDICAL DEVICES AND RADIOLOGICAL HEALTH

ACCREDITATION FUNCTIONS FOR MEDICAL DEVICES

Effective Date: October 29, 2018

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The officials listed below are authorized under Sections 523(a)(1) and (b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360m(a)(1) and (b)(2)(A)) to respond to a request for accreditation and to accredit persons for reviewing reports submitted under Section 510(k) of the Act (21 U.S.C. 360(k)) and making recommendations regarding the initial classification of devices:

1) Center for Devices and Radiological Health (CDRH) Director and Deputy Directors.

2) CDRH Office of In Vitro Diagnostics and Radiological Health (OIR) Director and Deputy Directors.

3) CDRH/OIR Division of Program Operations and Management (DPOM) Director, Deputy Directors, and Associate Directors.

B. The officials listed below are authorized under Sections 523(a)(2)(B) and (C) of the Act (21 U.S.C. 360m(a)(2)(B) and (C)) to make a determination with respect to the recommendation of an initial classification of a device; and to change the initial classification under Section 513(f)(1) of the Act (21 U.S.C. 360c(f)(1)) that is recommended by an accredited person to provide to such person, and the person who submitted the report under Section 510(k) of the Act (21 U.S.C. 360(k)) for the device, a statement explaining in detail the reasons for the change:

1) CDRH Director and Deputy Directors.

2) CDRH Office of Compliance (OC) Director and Deputy Directors.

3) CDRH/OC Division Directors, Deputy Division Directors, and Associate Division Directors.

4) CDRH Office of Device Evaluation (ODE) Director and Deputy Directors.

5) CDRH/ODE Division Directors, Deputy Division Directors, and Associate Division Directors.

6) CDRH/OIR Director and Deputy Directors.

7) CDRH/OIR Division Directors, Deputy Division Directors, and Associate Division Directors.

C. The officials listed below are authorized under Section 523(b)(2)(B) of the Act (21 U.S.C. 360m(b)(2)(B)) to suspend or withdraw accreditation of any person accredited to review reports and to make recommendations under Section 523 of the Act (21 U.S.C. 360m):

1) CDRH Director and Deputy Directors.

2) CDRH/OIR Director and Deputy Directors.

3) CDRH/OIR/DPOM Director, Deputy Directors, and Associate Directors.

D. The officials listed below are authorized under Section 523(b)(2)(C) of the Act (21 U.S.C. 360m(b)(2)(c)) to implement the measures described in that section to ensure that persons accredited under Section 523 of the Act (21 U.S.C. 360m) will continue to meet the standards of accreditation:

1) CDRH Director and Deputy Directors.

2) CDRH/OIR Director and Deputy Directors.

3) CDRH/OIR/DPOM Director, Deputy Directors, and Associate Directors.

2. REDELEGATION.

These officials may not further redelegate these authorities.

3. EFFECTIVE DATE.

The delegations become effective upon date of signature.

The Commissioner of Food and Drugs approved this delegation, via memorandum, on October 29, 2018.

STATUS	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	06/23/2009	N/a	OC/OO/ OM/OMP	Margaret A. Hamburg, M.D. Commissioner of Food and Drugs

STATUS	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Revision	11/22/2013	N/a	OMPT/CDRH/ OMO/DEMO/AMB	Walter S. Harris, Deputy Commissioner for Operations & Chief Operating Officer
Revision	10/29/2018	N/a	OMPT/CDRH/ OM/DWM	Scott Gottlieb, M.D. Commissioner of Food and Drugs

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