SMG 1410.604

FDA STAFF MANUAL GUIDES, VOLUME II – DELEGATIONS OF AUTHORITY

REGULATORY – RADIATION CONTROL

NOTIFICATION OF DEFECTS IN, AND REPAIR OR REPLACEMENT OF, ELECTRONIC PRODUCTS

Effective Date: August 22, 2016

1. AUTHORITY DELEGATED AND TO WHOM DELEGATED.

A. The following officials are authorized to perform all functions of the Commissioner of Food and Drugs (Commissioner), relating to notification of defects in or noncompliance of; repair, replacement or refund of; and approval of corrective action plans for electronic products under Section 534 of the Federal Food, Drug and Cosmetic Act (the Act) (21U.S.C. 360kk) and under Title 21, Code of Federal Regulations (CFR), Part 1000, Sections 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6:

1. Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), Office of Medical Products and Tobacco (OMPT).

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

3. Director and Deputy Directors, Division of Radiological Health (DRH), OIR, CDRH, OMPT.

B. The following officials are authorized to perform the functions described in Section A. above, as relates to assemblers of diagnostic x-ray systems, as defined in 21 CFR, Part 1000, Section 1020.30(b) and manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product, as defined in 21 CFR, Part 1000, Section 1040.20(b):

1. Regional Food and Drug Directors Office of Regulatory Affairs (ORA), Office of Global Regulatory Operations and Policy (OGROP).

2. District Directors, ORA, OGROP.

3. Director St. Louis Branch, Central District, ORA, OGROP.

C. The following officials are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under Section 535(e) of the act (21U.S.C. 360ll(e)) and under 21 CFR, Part 1000, Section 1003.11(a):

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

2. Director, Division of Radiological Health (DRH), OIR, CDRH, OMPT.

D. The following officials are authorized to perform the functions described in C. above, as relates to assemblers of diagnostic x-ray systems, as defined in 21 CFR, Part 1000, Section 1020.30(b) and manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp products, as defined in 21 CFR, Part 1000, Section 1040.20(b):

1. Chiefs of District Compliance Branches, ORA, OGROP.

2. REDELEGATION.

These officials may not further redelegate this authority.

3. EFFECTIVE DATE.

The delegations become effective upon date of signature. The Commissioner of Food and Drugs approved these delegations of authority, via memorandum, on August 22, 2016.

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	01/05/2010	N/a	CDRH/OMO/ DEMO/AMB	Margret A. Hamburg, M.D. Commissioner of Food and Drugs
Revision	08/22/2016	N/a	CDRH/OMO/ DEMO/AMB	Robert M. Califf, M.D. Commissioner of Food and Drugs

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