4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA-2013-N-1529]

Medical Device Classification Procedures; Change of Address; Technical Amendment

AGENCY: Food and Drug Administration; HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending the Medical Device Classification Procedures regulation to reflect a change in address for the Center for Devices and Radiological Health (CDRH). This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Karen Fikes, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5244, Silver Spring, MD 20993-0002, 301-796-9603.

SUPPLEMENTARY INFORMATION: FDA is amending our regulations in 21 CFR part 860 that set forth procedures for mailing reclassification petitions (§ 860.123 (21 CFR 860.123)) to revise the mailing address for CDRH. The current mailing address in the regulation for CDRH is as follows: Center for Devices and Radiological Health, Regulations Staff, 10903 New Hampshire Ave., Bldg. 66, Rm. 4438, Silver Spring, MD 20993-0002. The room number, 4438, has been changed; the new room number is G609. The mailing address is revised as

follows: Center for Devices and Radiological Health, Regulations Staff, Document Mail Center-WO66-G609, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002.

Sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(e) and (f); 360d(b); 360e(b), and 360j(l)), provide for the reclassification of a device and prescribe procedures to petition for reclassification. FDA provides procedures for the content and form of reclassification petitions submitted pursuant to § 860.123(b)(1) for devices regulated by CDRH. The address for submitting a reclassification petition for devices regulated by CDRH in § 860.123(b)(1) is amended to reflect the new room number. The addresses remain the same for the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research.

List of Subjects in 21 CFR Part 860

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 860 is amended as follows:

PART 860--MEDICAL DEVICE CLASSIFICATION PROCEDURES

1. The authority citation for part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

2. Revise § 860.123(b)(1) to read as follows:

§ 860.123 Reclassification petition: Content and form.

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(b) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Regulations

Staff, Document Mail Center-WO66-G609, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002; for devices regulated by the Center for Biologics Evaluation and Research, addressed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002; for devices regulated by the Center for Drug Evaluation and Research, addressed to the Food and Drug Administration, Center for Drug Evaluation and Research, Central Document Control Room, 5901-B Ammendale Rd., Beltsville, MD 20705-1266, as applicable.

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Dated: August 15, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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