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; Reclassification Petition: Content and Form; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations for petitioning for device reclassification to update mailing addresses for the petitions. This action is being taken to improve the accuracy of the regulations.

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

FOR FURTHER INFORMATION CONTACT: Nancy Pirt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4438, Silver Spring MD 20993-0002, 301-796-6254.

SUPPLEMENTARY INFORMATION: FDA is updating mailing addresses for device reclassification petitions (21 CFR 860.123). For devices regulated by the Center for Devices and Radiological Health, the room number is now 4438. In addition, the Center for Biologics Evaluation and Research has moved to a new location at FDA's White Oak Campus. The address remains the same for the Center for Drug Evaluation and Research. The regulations are being amended to ensure clarity and to improve the accuracy and readability of the regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment and a delayed effective date are unnecessary because these corrections are nonsubstantive.

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 21 CFR 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, 10903 New Hampshire Ave., Bldg. 66, rm. 4438, 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: December 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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