4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 814, 822, 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket No. FDA-2013-N-0011]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending certain medical device regulations to correct minor errors in the Code of Federal Regulations (CFR). This action is editorial in nature and is intended to provide accuracy and clarity to the Agency's regulations.

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is amending certain regulations in 21 CFR parts 814, 822, 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892. This action corrects minor spelling errors and outdated Web site addresses affecting certain regulations regarding medical devices.

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). These amendments are merely correcting nonsubstantive errors. FDA therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

FDA has determined under 21 CFR 25.30(i) that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required. In addition, FDA has determined that this final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 822

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 862

Medical devices.

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 868, 870, 872, 874, 876, 878, and 880

Medical devices.

21 CFR Part 882

Medical devices, Neurological devices.

21 CFR Part 884

Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 888

Medical devices.

21 CFR Part 890

Medical devices, Physical medicine devices.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

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

§§ 814.20, 822.7, 822.15, 862.1, 864.1, 866.1, 868.1, 870.1, 872.1, 874.1, 876.1, 878.1, 880.1, 882.1, 884.1, 886.1, 888.1, 890.1, and 892.1 [Amended]

1. In the table below, for each section indicated in the left column, remove the Web address indicated in the middle column from wherever it appears in the section, and add the Web address indicated in the right column:

Section	Remove	Add
814.20	http://www.fda.gov/cdrh/devadvice/pma/	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm
822.7	http://www.fda.gov/cdrh/ombudsman/dispute.html	http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOmbudsman/default.htm
822.15	www.fda.gov/cdrh/ombudsman/	http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOmbudsman/default.htm
862.1, 864.1, 866.1, 868.1, 870.1, 872.1, 874.1, 876.1, 878.1, 880.1, 882.1, 884.1, 886.1, 888.1, 890.1, and 892.1	http://www.fda.gov/cdrh/guidance.html	http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

PART 870--CARDIOVASCULAR DEVICES

2. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

3. Amend § 870.3600 by revising the second sentence in paragraph (a) to read as follows:

§ 870.3600 External pacemaker pulse generator.

(a) Identification. * * * This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. * * *

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4. Amend § 870.5300 by revising the section heading to read as follows:

§ 870.5300 DC-defibrillator (including paddles).

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PART 882--NEUROLOGICAL DEVICES

5. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

6. Amend § 882.5870 by revising the second sentence in paragraph (a) to read as follows:

§ 882.5870 Implanted peripheral nerve stimulator for pain relief.

(a) Identification. * * * The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

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PART 886--OPHTHALMIC DEVICES

7. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

8. Amend § 886.1120 by revising the section heading to read as follows:

§ 886.1120 Ophthalmic camera.

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Dated: March 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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