

(OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the guidance for the final rule. This guidance, "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters," references previously approved collections of information found in FDA regulations.

List of Subjects in 21 CFR Part 870

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 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

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

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

■ 2. Section 870.5100 is added to subpart F to read as follows:

§ 870.5100 Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter.

(a) *Standard PTCA Catheter*—(1) *Identification.* A PTCA catheter is a device that operates on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end. A PTCA balloon catheter has a single or double lumen shaft. The catheter features a balloon of appropriate compliance for the clinical application, constructed from a polymer. The balloon is designed to uniformly expand to a specified diameter and length at a specific pressure as labeled, with well characterized rates of inflation and deflation and a defined burst pressure. The device generally features a type of radiographic marker to facilitate fluoroscopic visualization of the balloon during use. A PTCA catheter is intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion. A PTCA catheter may also be intended for the treatment of acute myocardial infarction; treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

(2) *Classification.* Class II (special controls). The special control for this device is "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary

Angioplasty (PTCA) Catheters." See § 870.1(e) for the availability of this guidance document.

(b) *Cutting/scoring PTCA Catheter*—(1) *Identification.* A cutting/scoring PTCA catheter is a balloon-tipped catheter with cutting/scoring elements attached, which is used in those circumstances where a high pressure balloon resistant lesion is encountered. A cutting/scoring PTCA catheter is intended for the treatment of hemodynamically significant coronary artery stenosis for the purpose of improving myocardial perfusion. A cutting/scoring PTCA catheter may also be indicated for use in complex type C lesions or for the treatment of in-stent restenosis.

(2) *Classification.* Class III (premarket approval). As of May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed. See § 870.3.

Dated: August 31, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010-22304 Filed 9-7-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AN54

Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease); Correction

AGENCY: Department of Veterans Affairs.

ACTION: Final rule; correction.

SUMMARY: The Department of Veterans Affairs (VA) published in the **Federal Register** on August 31, 2010, a document amending the adjudication regulations concerning the presumptive service connection for certain diseases based upon the most recent National Academy of Sciences Institute of Medicine committee report, Veterans and Agent Orange: Update 2008. In the preamble of that document, VA inadvertently included an incorrect Web site address. This document corrects the Web site address.

DATES: *Effective Date:* This correction is effective September 8, 2010.

FOR FURTHER INFORMATION CONTACT: Janet Coleman, Office of Regulation Policy and Management, Department of Veterans Affairs, 810 Vermont Avenue,

NW., Washington, DC 20420, (202) 461-4902 (This is not a toll-free number.).

SUPPLEMENTARY INFORMATION: On August 31, 2010, VA published in the **Federal Register** (75 FR 53202), an amendment to 38 CFR 3.309 to add hairy cell leukemia and other chronic B-cell leukemias, Parkinson's disease and ischemic heart disease to the list of diseases subject to presumptive service connection based on herbicide exposure. On page 53215 of that document, in the third column, second paragraph, we inadvertently provided a Web site of: "http://vaww1.va.gov/ORPM/FY_2010_Published_VA_Regulations.asp", which is corrected to read: "http://www1.va.gov/ORPM/FY_2010_Published_VA_Regulations.asp".

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Approved: September 2, 2010.

Robert C. McFetridge,

Director, Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

[FR Doc. 2010-22281 Filed 9-7-10; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AH95

Medical; Nonsubstantive Miscellaneous Changes; Correction

AGENCY: Department of Veterans Affairs.

ACTION: Correcting amendment.

SUMMARY: The Department of Veterans Affairs (VA) published a final rule in the **Federal Register** on May 13, 1996 (61 FR 21964), amending its medical regulations in 38 CFR part 17 by making a number of nonsubstantive changes. Specifically, section numbers were redesignated, redundant and obsolete material was removed, certain position and organizational titles were changed, and material previously deleted was restored. The document contained an error in an amendatory instruction. We removed portions of § 17.31 and inadvertently redesignated § 17.31(b)(5) as the new § 17.31, creating two sections for § 17.31. This document will correct that error by removing the second, obsolete § 17.31.

DATES: *Effective Date:* September 8, 2010.