(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.

FOR FURTHER INFORMATION CONTACT: Ethan Kalett, Director of Regulatory Affairs (107B), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420; (202) 461–7633. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On May 13, 1996, VA published a final rule in the **Federal Register** (61 FR 21964) amending its medical regulations in 38 CFR part 17 by making a number of nonsubstantive changes. In the document, we removed § 17.31 (a), (b) introductory text and (b)(1) through (b)(4), (b)(6), (b)(7), and (c), leaving (b)(5) and (d). Inadvertenly, we then redesignated § 17.31(b)(5) as § 17.31, creating a second § 17.31. The second § 17.31 is obsolete. This document corrects the error by removing the second § 17.31 from 38 CFR part 17.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved:

Robert C. McFetridge,

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

■ For the reason set out in the preamble, VA is correcting 38 CFR part 17 as follows.

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, 1721, and as stated in specific sections.

■ 2. In part 17, remove the second § 17.31.

[FR Doc. 2010–22252 Filed 9–7–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA–R03–OAR–2010–0431; FRL–9197–5]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Withdrawal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Withdrawal of direct final rule.

SUMMARY: Due to an adverse comment, EPA is withdrawing the direct final rule to extend the attainment date from June 15, 2010 to June 15, 2011 for the Baltimore nonattainment area, which is classified as moderate for the 1997 8-hour ozone national ambient air quality standard (NAAQS). In the direct final rule published on July 23, 2010, we stated that if we received any adverse comments by August 23, 2010, the rule would be withdrawn and would not take effect. EPA received an adverse comment within the comment period. EPA will address the comment received in a subsequent final action based upon the proposed action also published on July 23, 2010 (75 FR 43114). EPA will not institute a second comment period on this action.

DATES: *Effective Date:* The direct final rule is withdrawn as of September 8, 2010.

FOR FURTHER INFORMATION CONTACT: Gregory Becoat, (215) 814–2036, or by e-mail at *becoat.gregory@epa.gov.*

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: August 18, 2010.

Shawn M. Garvin,

Regional Administrator, Region III.

■ Accordingly, the amendments to § 81.321, published in the direct final rule on July 23, 2010 (75 FR 43069), are withdrawn as of September 8, 2010.

[FR Doc. 2010–22344 Filed 9–7–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL–9197–6]

Ocean Dumping; Guam Ocean Dredged Material Disposal Site Designation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is designating the Guam Deep Ocean Disposal Site (G–DODS) as a permanent ocean dredged material disposal site (ODMDS) located offshore of Guam. Dredging is essential for maintaining safe navigation at port and naval facilities in Apra Harbor and other locations around Guam. Beneficial re-use of dredged material (*e.g.,* for habitat creation, construction material, or landfill cover) is preferred over ocean disposal. However, not all dredged materials are suitable for beneficial re-use, and not all suitable materials can be re-used or stockpiled for future use given costs, logistical constraints, and capacity of existing land disposal or re-handling sites. Therefore, there is a need to designate a permanent ODMDS offshore of Guam. Disposal operations at the site will be limited to a maximum of 1 million cubic yards (764,555 cubic meters) per calendar year and must be conducted in accordance with the Site Management and Monitoring Plan and any project-specific permit conditions. The designated ODMDS will be monitored periodically to ensure that the site operates as expected.

DATES: Effective October 8, 2010.

FOR FURTHER INFORMATION CONTACT: Mr. Allan Ota, Dredging and Sediment Management Team, U.S. Environmental Protection Agency, Region IX (WTR–8), 75 Hawthorne Street, San Francisco, CA 94105, telephone (415) 972–3476 or FAX: (415) 947–3537 or E-mail: *ota.allan@epa.gov.*

SUPPLEMENTARY INFORMATION: The supporting document for this site designation is the Final Environmental Impact Statement for the Designation of an Ocean Dredged Material Disposal Site Offshore of Guam. This document is available for public inspection at the following locations:

1. Guam EPA's Main Office, 17–3304 Mariner Avenue, Tiyan, Guam 96913.

2. Nieves M. Flores Memorial Public Library, 254 Martyr Street, Hagatna, Guam 96910.

3. Barrigada Public Library, 177 San Roque Drive, Barrigada, Guam 96913.