betamethasone acetate equivalent to 0.89 mg betamethasone alcohol.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill one or two drops of solution in the conjunctival sac three or four times a day.

(2) *Indications for use.* For treatment of external bacterial infections of the eye (conjunctiva and cornea).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: September 1, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010–22276 Filed 9–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2000–P–0924] (formerly Docket No. FDA–2000–P–1533)

Cardiovascular Devices; Reclassification of Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the device type, standard percutaneous transluminal coronary angioplasty (PTCA) catheters, from class III (premarket approval) into class II (special controls). Cutting/scoring PTCA catheters remain in class III and continue to require premarket approval applications (PMAs). FDA is reclassifying these devices in accordance with the Federal Food, Drug, and Cosmetic Act (the act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" that will serve as the special control for the reclassified device type.

DATES: This final rule is effective October 8, 2010.

FOR FURTHER INFORMATION CONTACT: Kathryn O'Callaghan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6349.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f)) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)); or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification (510(k)) procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a PMA until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of postamendments devices is governed by section 513(f)(3) of the act (21 U.S.C.360c(f)(3)). This section states that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or that a manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device into class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(3)(B)(i) of the act, the Secretary may, for good cause shown, refer a petition to a device panel. If a petition is referred to a panel, the panel shall make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed.

II. Regulatory History of the Device

The PTCA catheter is a postamendments device classified into class III under section 513(f)(1) of the act. Therefore, the device cannot be placed in commercial distribution unless it is subject to an approved premarket approval application (PMA) under section 515 of the act (21 U.S.C. 360e) or is reclassified.

On September 21, 2000, FDA filed a petition submitted under section 513(f)(3) of the act from COOK requesting reclassification of PTCA catheters from class III into class II. This reclassification petition did not include cutting or scoring PTCA catheters. In order to reclassify the PTCA catheter into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and

effectiveness of the device for its intended use.

The COOK petition requested reclassification of PTCA catheters from class III to class II when indicated 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. Consistent with the act and the regulation, FDA referred the petition to the Panel for its recommendation on the requested changes in classification. FDA also asked the Circulatory System Devices Panel for its recommendation on the reclassification of PTCA catheters when used for treatment of acute myocardial infarction (MI), treatment of in-stent restenosis (ISR) and/or post-deployment stent expansion.

III. Device Description

FDA identifies this generic type of device, the subject of this reclassification, as follows: *Standard Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter.* 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.

FDA is also issuing the following identification for the devices that will remain in class III: 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.

IV. Recommendation of the Panel

At a public meeting on December 4, 2000, the Panel recommended (seven to one) that PTCA catheters be reclassified from class III to class II, when indicated 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; or for treatment of acute myocardial infarction. The Panel did not recommend reclassification for PTCA catheters indicated for the treatment of in-stent restenosis and/or post-deployment stent expansion. The Panel recommended a guidance document, labeling, and postmarket surveillance as special controls. The Panel stated that the special controls will diminish some of the risks to health associated with certain PTCA catheters. The guidance document and labeling controls are intended to ensure the appropriate performance and use of the device by physicians. The Panel recommended postmarket surveillance as a special control to confirm that the other special controls being applied to these devices would be sufficient to ensure that there would not be an increase in adverse consequences to patients. In summary, the Panel believed that class II with special controls would provide reasonable assurance of the safety and effectiveness of the device.

The Panel recommended that PTCA catheters for the treatment of in-stent restenosis and/or post-deployment stent expansion not be included because of a lack of sufficient information about this use. Since the Panel meeting, however, additional data regarding this use have become available and have been reviewed by the agency.

FDA considered the Panel's recommendations and tentatively agreed that PTCA catheters, other than cutting/scoring PTCA catheters, should be reclassified from class III into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

Although the Panel included the possibility of requiring postmarket surveillance in their recommendation, FDA did not agree that specific postmarket surveillance such as device tracking or postapproval studies are needed for PTCA catheters. FDA believes that periodic assessment of adverse event reports through medical device reporting submitted to the agency is sufficient to address adverse effects caused by these devices and is the least burdensome way to gather this data for PTCA catheters. This practice is consistent with the manner in which these devices have been regulated as class III devices since the Panel meeting.

Further, after a review of adverse event reports submitted to FDA's Manufacturer and User Facility Device Experience (MAUDE) Database, the agency believes that the types of risks associated with the use of PTCA catheters for the treatment of in-stent restenosis and/or post-deployment stent expansion are similar enough to the risks associated with treatment of de novo lesions, such that the special controls discussed at the Panel meeting, with the addition of recommendations for specific nonclinical performance testing and the recommendation that in-stent restenosis patients be included in the clinical evaluation, when necessary, are adequate to control the risks to health for these devices.

Accordingly, in the **Federal Register** of May 30, 2008 (73 FR 31123), FDA issued the Panel's recommendation for public comment. FDA did not receive any comments regarding the Panel's recommendation. Elsewhere in this issue of the **Federal Register**, comments received regarding the draft guidance document are addressed in the notice of availability announcing the special controls guidance document.

V. FDA's Conclusion

After reviewing the data in the petition and presented at the Panel meeting, and after considering the Panel's recommendation and the comments on the notice of panel recommendation, FDA has determined that the device type, standard percutaneous transluminal coronary angioplasty (PTCA) catheters, can be reclassified from class III into class II.

On August 19, 2010, FDA issued an order to the petitioner reclassifying the devices into class II (special controls). The order also identified the special control applicable to these devices as a guidance document entitled "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters." This class II special controls guidance document is now the special control for this device type.

An alternative approach to the special controls guidance document may be used if such approach satisfies the applicable statute and regulations.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for this device type will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Accordingly, as required by 21 CFR 860.134(b)(6) and (b)(7) of the regulations, FDA is announcing the reclassification of the standard percutaneous transluminal coronary angioplasty (PTCA) catheters, from class III into class II. In addition, FDA is issuing this final rule to codify the reclassification of the device by adding new § 870.5100.

VI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action 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.

VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device type, from class III to class II, will relieve manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because reclassification will reduce regulatory costs with respect to this device, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

Based on an assessment of identified risks associated with the use of PTCA catheters, FDA finds the requirements associated with a premarket approval as a class III device do not provide an added public health benefit over those that would result from the requirements under a class II (with special controls). At the same time, PTCA catheter manufactures, as makers of class III devices, bear all the costs associated with a premarket approval, including the cost of submitting the premarket approval application (PMA) and payment of user fees. One previously published estimate (in 73 FR 7497) suggests that the costs to prepare a PMA could potentially reach $1,000,000, in addition to user fees of $217,787 in FY (fiscal year) 2010.

In contrast, if reclassification becomes final, manufacturers of a PTCA catheter would pay a user fee of $4,007 for a 510(k) submission in FY 2010. While we do not have data to estimate the cost of preparing a 510(k) submission, several different factors indicate that it would be less than the cost of a PMA. For example, a firm does not have to submit manufacturing information in its 510(k), which is required for a PMA application, thereby reducing the burden and documentation needed. Given the ability to evaluate nonclinical testing in a direct comparison to a predicate device in a 510(k), FDA anticipates that most new PTCA catheters will not require clinical data to support 510(k) clearance, whereas all PMAs have to include some form of clinical data to support PMA approval. This difference will result in a significant reduction in cost for the device manufacturer. A PMA also requires the sponsor to prepare a draft summary of safety and effectiveness document, which is not required for a 510(k).

Based on the most recent 5 years, FDA estimates the following annual number of submissions received for PTCA catheters: 15 "30-day Notice" PMA supplements, 1 "Normal 180-day Track" PMA supplement, and 2 "Real-Time Process" PMA supplements. (Note: FDA has not received any "Panel-Track" supplements or original PMA submissions for this device in the past 5 years.) A "30-day Notice" is submitted for changes to a manufacturing process or method and assessed a user fee of $3,485 in FY 2010. When reclassification is final, these types of changes will not require clearance prior to the firm making the change in the majority of cases. Modifications to the method of manufacture of a device could require submission of a 510(k) if the changes could significantly affect the safety or effectiveness of the device, such as those that would currently require a "Real-Time Process" or "Panel-Track" PMA supplement. Based on FDA's experience, submission of a 510(k) for a modification to the method of manufacturing would be rare.

In summary, this device reclassification would reduce the existing burden on manufacturers of PTCA catheters. The application of class II (with special controls) requirements would be consistent with the principle of applying the least degree of regulatory control necessary to provide reasonable assurance of safety and effectiveness.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe *** a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain state requirements "different from or in addition to" certain Federal requirements applicable to devices. (See section 512 of the act (21 U.S.C. 360k); *Medtronic* v. *Lohr*, 518 U.S. 470 (1996); *Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008)). The special controls established by this final rule create "requirements" for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. *Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997).

IX. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget

(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.