Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for KALYDECO (U.S. Patent No. 7,495,103) from Vertex Pharmaceuticals Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 22, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of KALYDECO represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for KALYDECO is 2,121 days. Of this time, 2,015 days occurred during the testing phase of the regulatory review period, while 106 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* April 13, 2006. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 13, 2006.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* October 18, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for KALYDECO (NDA 203188) was submitted on October 18, 2011.

3. *The date the application was approved:* January 31, 2012. FDA has verified the applicant's claim that NDA 203188 was approved on January 31, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 0 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 29, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 26, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12561 Filed 5–29–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0851]

Determination of Regulatory Review Period for Purposes of Patent Extension; PROGENSA PCA3 ASSAY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PROGENSA PCA3 ASSAY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device, PROGENSA PCA3 ASSAY. PROGENSA PCA3 ASSAY is an in vitro nucleic acid amplification test. The assay measures the concentration of prostate cancer gene 3 (PCA3) and prostate specific antigen (PSA) ribonucleic acid (RNA) molecules and calculates the ratio of PCA3 RNA molecules to PSA RNA molecules (PCA3 Score) in post-digital rectal exam first catch male urine specimens. The PROGENSA PCA3 ASSAY is indicated for use in conjunction with other patient information to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be

recommended by a urologist based on current standard of care, before consideration of PROGENSA PCA3 ASSAY results. A PCA3 score <25 is associated with a decreased likelihood of a positive biopsy. Prostatic biopsy is required for diagnosis of cancer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PROGENSA PCA3 ASSAY (U.S. Patent No. 7,008,765) from The Johns Hopkins University & The Stichting Katholieke Universiteit, The University Medical Centre Nijmegen, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 1, 2013, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of PROGENSA PCA3 ASSAY represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PROGENSA PCA3 ASSAY is 936 days. Of this time, 383 days occurred during the testing phase of the regulatory review period, while 553 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective or if an exemption is not required, the date an institutional review board under section 520(g)(3) of the FD&C Act (21 U.S.C. 360j(g)(3)) approved the clinical investigation of the device in humans:* July 24, 2009. FDA has confirmed the applicant's claim that no investigational device exemption (IDE) was required under section 520(g) of the FD&C Act for human tests to begin. Institutional review board (IRB) approval was required under section 520(g)(3) of the FD&C Act and became effective on July 24, 2009.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 10, 2010. FDA has verified the applicant's claim that the premarket approval application (PMA) for PROGENSA PCA3 ASSAY (PMA 100033) was initially submitted August 10, 2010.

3. *The date the application was approved:* February 13, 2012. FDA has verified the applicant's claim that PMA P100033 was approved on February 13, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 745 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 29, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 26, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12562 Filed 5–29–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Supplemental Bulletin updates the OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees that published in the **Federal Register** on November 22, 2005 (70 FR 70623).

SUPPLEMENTARY INFORMATION:

I. Introduction

Patients who cannot afford their cost-sharing obligations for prescription drugs may be able to obtain financial assistance through a patient assistance program (PAP). PAPs have long provided important safety net assistance to such patients, many of whom have chronic illnesses and high drug costs. Many PAPs also present a risk of fraud, waste, and abuse with respect to Medicare and other Federal health care programs. We issued a Special Advisory Bulletin regarding PAPs in 2005 [1] (the 2005 SAB) in anticipation of questions likely to arise in connection with the Medicare Part D benefit. In the 2005 SAB, we addressed different types of PAPs and stated that we believed lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs.[2] We also noted in the 2005 SAB that we could only speculate on fraud and abuse risk areas, because the Part D benefit had not yet begun. This Supplemental Special Advisory Bulletin (Supplemental Bulletin) is based on experience we have gained in the intervening years; it is not intended to replace the 2005 SAB, nor does it replace other relevant guidance, such as the 2002 OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries.[3]

We continue to believe that properly structured PAPs can help Federal health care program beneficiaries. This Supplemental Bulletin provides additional guidance regarding PAPs operated by independent charities (Independent Charity PAPs) that provide cost-sharing assistance for

[1] OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 FR 70623 (Nov. 22, 2005), available at: *http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf.*

[2] The 2005 SAB focused on PAPs under the then-upcoming Part D program, but the guidance also referenced co-payment assistance programs for drugs covered under Medicare Part B. Although these Medicare programs differ, and the types of PAPs may differ, the principles set forth in the 2005 SAB and herein apply regardless of which Federal health care program (as defined in section 1128B(f) of the Social Security Act (the Act)) covers the drugs.

[3] The 2002 OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries is available at: *http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.*