and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. 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 (for example, 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 human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product LUCENTIS (ranibizumab). LUCENTIS is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for LUCENTIS (U.S. Patent Nos. 6,407,213; 6,884,879; and 7,060,269) from Genentech, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In letters dated July 24, 2007, and November 21, 2007, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of LUCENTIS represented the first permitted commercial marketing or use of the product. Shortly 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 LUCENTIS is 2,430 days. Of this time, 2,247 days occurred during the testing phase of the regulatory review period, while 183 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 (21 U.S.C. 355(i)) became effective*: November 6, 1999. The applicant claims October 7, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 6, 1999, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262)*: December 30, 2005. The applicant claims December 29, 2005, as the date the biologics license application (BLA) for LUCENTIS (BLA 125156/0) was initially submitted. However, FDA records indicate that BLA 125156/0 was submitted on December 30, 2005.

3. *The date the application was approved*: June 30, 2006. FDA has verified the applicant's claim that BLA 125156/0 was approved on June 30, 2006.

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 applications for patent extension for U.S. Patent Nos. 6,407,213; 6,884,879; and 7,060,269, this applicant seeks 378 days; 307 days or 17 days, respectively, 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**) written or electronic comments and ask for a redetermination by July 28, 2008. 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 25, 2008. 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 8, 2008.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E8–12007 Filed 5–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–M–0467] (formerly Docket No. 2007M–0408), [Docket No. FDA–2007–M–0481] (formerly Docket No. 2007M–0467), [Docket No. FDA–2007–M–0480] (formerly Docket No. 2007M–0409), [Docket No. FDA–2007–M–0472] (formerly Docket No. 2007M–0413), [Docket No. FDA–2007–M–0468] (formerly Docket No. 2007M–0446), [Docket No. FDA–2007–M–0494] (formerly Docket No. 2007M–0380), [Docket No. FDA–2007–M–0493] (formerly Docket No. 2007M–0411), [Docket No. FDA–2007–M–0492] (formerly Docket No. 2007M–0410), [Docket No. FDA–2007–M–0490] (formerly Docket No. 2007M–0415), [Docket No. FDA–2007–M–0491] (formerly Docket No. 2007M–0447]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in Table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Samie Allen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4013.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from October 1, 2007, through December 31, 2007. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2007, THROUGH DECEMBER 31, 2007.

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P000009 (S4)/2007M–0408	Biotronik, Inc.	TACHOS DR ATRIAL TX IMPLANTABLE CARDIOVERTER DEFIBRILLATOR ICD SYSTEM	September 9, 2002
P060031/2007M–0467	Bio-Rad Laboratories	BIO–RAD MONOLISA ANTI–HBC EIA	April 27, 2007
P060005/2007M–0409	Siemens Medical Solutions Diagnostics	IMMULITE/IMMULITE 1000 & IMMULITE 2000 FREE PSA ASSAYS	May 11, 2007
P060017/2007M–0413	Veridex, LLC	GENESEARCH BREAST LYMPH NODE (BLN) ASSAY	July 16, 2007
P040040/2007M–0446	AGA Medical Corp.	AMPLATZER MUSCULAR VSD	September 7, 2007
P070009/2007M–0380	Obtech Medical GMBH	REALIZE ADJUSTABLE GASTRIC BAND MODEL 2200–X	September 28, 2007
P070012/2007M–0411	Medtronic Vascular	EXPONENT SELF-EXPANDING CAROTIC STENT SYSTEM WITH OVER THE WIRE OR RAPID EXHANGE DELIVERY SYSTEM	October 23, 2007
P060038/2007M–0410	Carbomedics, Inc.	MITROFLOW AORTIC PERICARDIAL HEART VALVE	October 23, 2007
H990002/2007M–0415	Genzyme Biosurgery	EPICEL (CULTURED EPIDERMAL AUTOGRAFTS)	October 25, 2007
P060035/2007M–0447	Abbott Laboratories	ARCHITECT CORE-M REAGENT KIT/CALIBRATORS/CONTROLS	November 6, 2007

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: May 16, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–12012 Filed 5–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; The Prevalence and Incidence of HIV Molecular Variants and Their Correlation With Risk Behaviors and HIV Treatment in Brazilian Blood Donors

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The Prevalence and Incidence of HIV Molecular Variants and Their Correlation With Risk Behaviors and HIV Treatment in Brazilian Blood Donors. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Establishing and monitoring viral prevalence and incidence rates, and identifying risk behaviors for HIV incidence among blood donors, are critical to assessing and reducing risk of HIV transmission through blood transfusion. Identifying donation samples from donors with recent HIV infection is particularly critical as it enables characterization of