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

the viral subtypes currently transmitted within the screened population and hence most likely to ''break-through'' routine screening measures (*i.e.*, peri-seroconversion window period donations). Molecular surveillance of incident HIV infections in blood donors not only characterizes genotypes of recently infected donors for purposes of blood safety, but also enables documentation of the rates of primary transmission of anti-viral drug resistant strains in the community, serving a public health role in identifying new HIV infections for anti-retroviral treatment. Both a prospective surveillance and a case-control design are proposed to enroll all eligible HIV seropositives detected at three blood centers in Brazil (São Paulo, Belo Horizante, and Recífe) plus a satellite center in Rio de Janeiro. A comparison of epidemiological risk profiles will be made between the seropositive donors and a group of randomly selected seronegative donors.

There are three study aims. Laboratory studies (LS–EIA testing and sequencing of pol region) on linked specimens from all enrolled HIV cases, will allow for estimation of HIV prevalence and incidence relative to genotype and putative route of infection. Data derived from molecular genotyping, including drug resistant genotypes, will be provided, along with counseling, to all enrolled HIV positive donors to facilitate their clinical care via referral to the Brazilian national HIV treatment system. Our findings will be compared to trends in prevalence, incidence and molecular variants from studies of the general population and high risk populations in Brazil, thus allowing for broad monitoring of the HIV epidemic in Brazil and assessment of the impact of donor selection criteria on these parameters. Finally, HIV cases and a group of controls, through responses to a questionnaire, will provide data on HIV risk behaviors among prospective blood donors. This HIV risk behavior data will be used as covariates in the molecular surveillance analyses described above, as well as aid in assessing whether modifications may be needed to Brazil's routine blood center operational donor screening questionnaire.

The study participants will return to their local blood center for the administration of an informed consent form, explaining the confidential nature of the research study as well as the risks and benefits to their participation. Once enrolled, they will be asked to complete the self-administered risk factor questionnaire. In addition, a small blood sample will be collected from each HIV seropositive participant to be used for the genotyping and drug resistance testing. The results of the drug resistance testing will be communicated back to the seropositive participants during an in-person counseling session at the blood center. Defining prevalence and incidence in blood donors and residual risk of HIV transmission by transfusions may lead to new regulations and blood safety initiatives in Brazil. The data can be used to project the yield, safety impact and cost effectiveness of implementing enhanced testing strategies such as combination antigen-antibody assays and/or NAT. Determination of HIV risk factors in donors (first time versus repeat donor status; volunteer versus replacement status; demographics and risk behaviors) will support policy discussions over strategies to recruit the safest possible donors in Brazil. The findings from this project will also complement similar monitoring of HIV prevalence, incidence, transfusion risk and molecular variants in the U.S. and other funded international REDS-II sites, thus allowing direct comparisons of these parameters on a global level.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents*: Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 2,000; *Estimated Number of Responses per Respondent*: 1; *Average Burden of Hours per Response*: 0.40 (including administration of the informed consent form and questionnaire completion instructions); and *Estimated Total Annual Burden Hours Requested:* 800. The annualized cost to respondents is estimated at: $5,200 (based on $6.50 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
2,000	1	0.40	800

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 9144, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892–7950, or call 301–435–0065, orE-mail your request to *nemog@nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: May 20, 2008.

George Nemo,

Project Officer, NHLBI, National Institutes of Health.

[FR Doc. E8–11921 Filed 5–28–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S.