Staphylococcus aureus, and *Salmonella,* Ms. Izurieta failed to do so. Ms. Izurieta also distributed shipments of dairy products after learning that FDA had slated specific shipments for examination due to concerns of adulteration with *E. coli, S. aureus,* and *Salmonella.* Ms. Izurieta failed to redeliver for destruction and exportation shipments of dairy products that FDA had determined to be adulterated with *E. coli, S. aureus,* and *Salmonella* and that were not authorized for entry into the United States. Ms. Izurieta then distributed dairy products that were adulterated and not authorized for entry into the United States. This conduct was in violation of 18 U.S.C. 545.

From approximately April 18, 2007, and continuing to approximately December 7, 2010, Ms. Izurieta fraudulently and knowingly imported and brought into the United States merchandise contrary to law. Further, Ms. Izurieta failed to redeliver, export, and destroy with FDA supervision the dairy products and other food products contained in these shipments after receiving notice from FDA regarding concerns about the adulteration of these products with *E. coli, S. aureus,* and/or *Salmonella.*

As a result of her conviction, on September 28, 2011, FDA sent Ms. Izurieta a notice by certified mail proposing to debar her for a period of 30 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Ms. Izurieta was convicted of six felony counts under Federal law for conduct relating to the importation into the United States of an article of food because she conspired to and did commit offenses related to the importation of dairy products and other products into the United States, and a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act that Ms. Izurieta should be subject to the maximum possible period of debarment. The proposal also offered Ms. Izurieta an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Izurieta failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Ms. Anneri Izurieta has been convicted of six felony counts under Federal law for conduct relating to the importation of an article of food into the United States and that she is subject to the full period of debarment.

As a result of the foregoing finding, Ms. Izurieta is debarred for a period of 30 years from importing articles of food or offering such articles for import into the United States, effective (see **DATES**). Under section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Ms. Izurieta is a prohibited act.

Any application by Ms. Izurieta for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2011–N–0589 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 4, 2012.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012–542 Filed 1–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2011–M–0502, FDA–2011–M–0503, FDA–2011–M–0563, FDA–2011–M–0564, FDA–2011–M–0600, FDA–2011–M–0601, FDA–2011–M–0630, and FDA–2011–M–0707]

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: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993–0002, (301) 796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C 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 FD&C 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 July 1, 2011, through September 30, 2011. 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 JULY 1, 2011, THROUGH SEPTEMBER 30, 2011

PMA No. Docket No.	Applicant	Trade name	Approval date
P100031, FDA–2011–M–0502.	Roche Diagnostics Corp.	ELECSYS ANTI–HBC IMMUNOASSAY & ELECSYS PRECICONTROL ANTI–HBC.	June 22, 2011.
P100032, FDA–2011–M–0503.	Roche Diagnostics Corp.	ELECSYS ANTI–HBC IMMUNOASSAY, ELECSYS PRECICONTROL ANTI–HBC FOR USE ON THE ELECSYS 2010 IMMUNOASSAY ANALYZER.	June 27, 2011.
P100001, FDA–2011–M–0563.	Ortho-Clinical Diagnostics, Inc..	VITROS IMMUNODIAGNOSTICS PRODUCTS ANTI–HBE REAGENT PACK, VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI–HBE CALIBRATOR, AND VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI–HBE CONTROLS.	July 20, 2011.
P110001, FDA–2011–M–0564.	Abbott Vascular	RX HERCULINK ELITE RENAL STENT SYSTEM	July 20, 2011.
P100044, FDA–2011–M–0600.	Intersect ENT	PROPEL	August 11, 2011.
P110020, FDA–2011–M–0601.	Roche Molecular Systems, Inc..	COBAS 4800 BRAF V600 MUTATION TEST	August 17, 2011.
P110012, FDA–2011–M–0630.	Abbott Molecular, Inc.	VYSIS ALK BREAK APART FISH PROBE KIT; VYSIS PARAFFIN PRETREATMENT IV & POST HYBRIDIZATION WASH BUFFER KIT; PROBECHEK ALK NEGATIVE CONTROL SLIDES; AND PROBECHEK ALK POSITIVE CONTROL SLIDES.	August 26, 2011.
H100006, FDA–2011–M–0707.	Synapse Biomedical, Inc.	NEURX DPS DIAPHRAGM PACING SYSTEM	September 28, 2011.

II. Electronic Access

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

Dated: January 9, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–537 Filed 1–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil

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: Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil. *Type of Information Collection Request: Extension* (OMB No. 0925–0597). *Need and Use of Information Collection:* Establishing and monitoring viral prevalence and incidence rates, and identifying behavioral risk behaviors for HIV infection among donors are critical steps to assessing and reducing risk of HIV transmission through blood transfusion. Detecting donors with recently acquired HIV infection is particularly critical as it enables characterization of the viral subtypes currently transmitted within the screened population. In addition to characterizing genotypes of recently infected donors for purposes of blood safety, molecular surveillance of incident HIV infections in blood donors serves important public health roles by identifying new HIV infections for anti-retroviral treatment, and enabling documentation of the rates of primary transmission of anti-viral drug resistant strains in the community. This study is a continuation of a previous research project which enrolled eligible HIV positive blood donors and analyzed HIV molecular variants and their association with risk.

This previous project was conducted by the NHLBI Retrovirus Epidemiology Donor Study—II (REDS–II) International Brazil program and included not only data collection on HIV seropositive donors but also collection of risk factor data on uninfected donors. The current Recipient Epidemiology and Donor Evaluation Study—(REDS–III) research proposal is a continuation of the previous REDS–II project at the same four blood centers in Brazil, located in the cities of Sao Paulo, Recife, Rio de Janeiro and Belo Horizonte, but this time restricted to the study of HIV-positive subjects.

The primary study aims are to continue monitoring HIV molecular variants and risk behaviors in blood donors in Brazil, and to evaluate HIV subtype and drug resistance profiles among HIV positive donors according to HIV infection status (recent versus long-standing infection), year of donation, and site of collection. Additional study objectives include determining trends in HIV molecular variants and risk factors associated with HIV infection by combining data collected in the previous REDS–II project with that which will be obtained in the planned research activities.

Nucleic acid testing (NAT) testing for HIV is currently being implemented in Brazil. It will be important to continue to collect molecular surveillance and risk factor data on HIV infections, especially now that infections that might not have been identified by serology testing alone could be recognized through the use of NAT. NAT-only infections represent very recently acquired infections. The NAT assay will be used at the four REDS–III blood centers in Brazil during the planned research activities. In addition, in order to distinguish between recent seroconversion and long-standing infection, samples from all HIV antibody- dual reactive donations and/or NAT positive donations will be tested by the Recent Infection Testing