Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after April 10, 2014. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information on in vitro and in vivo thrombogenicity test methods. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is May 14, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., EST, Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

SUPPLEMENTARY INFORMATION:

I. Background

Thrombosis, or blood clot formation, is a major complication in the use of blood-contacting medical devices. Thrombosis often leads to device malfunction and severe adverse events such as stroke or myocardial infarction. To improve device quality and reduce the occurrence of thrombus formation, it is important to fully assess the thrombogenic potential of a medical device prior to clinical use and make material or geometrical modifications if necessary.

The current thrombogenicity test paradigm relies heavily on animal studies. For implanted devices, where animal studies are often conducted to assess safety and possible effectiveness, thrombogenicity endpoints can also be included. However, for many interventional devices, where other animal studies are not commonly requested, FDA has traditionally recommended a 4-hour in vivo canine thrombogenicity test model for assessment of thrombogenic potential. Because there have been questions about the consistency, reliability, and clinical relevance of this 4-hour canine thrombogenicity model, FDA is interested in optimizing the conduct of this in vivo test and/or identifying alternative in vitro tests that provide equivalent or improved clinical insight into the potential for thrombogenicity of medical devices while minimizing expenses and animal use, if possible.

This workshop will bring together academia, industry professionals, and FDA regulators to discuss the advantages, limitations, and optimization of both in vivo and in vitro thrombogenicity test methods, and identify alternative in vitro tests that show promising clinical relevance. We will discuss testing methods related to a broad range of blood contacting devices, especially for cardiovascular applications. Ideas generated during this workshop may facilitate development of new guidance and/or standards for thrombogenicity testing that optimize current in vivo methods and/or utilize in vitro methods.

II. Topics for Discussion at the Public Workshop

FDA seeks to address and receive comments on the following topics:

1. Strengths, weaknesses, and optimization of in vivo thrombogenicity test methods;

2. Current methodologies for conducting in vitro thrombogenicity testing (e.g., blood conditions, static versus dynamic methods, and different test endpoints);

3. Correlation between in vitro/in vivo thrombogenicity test results and clinical outcomes;

4. Special testing considerations for catheters, stents, grafts, ventricular assist devices, and bypass circuit components.

Dated: March 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05411 Filed 3–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0229]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that VIMIZIM (elosulfase alfa), manufactured by BioMarin Pharmaceutical, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Vicki Moyer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6467, Silver Spring, MD 20993–0002, 301–796–2200, FAX: 301–796–9855, *vicki.moyer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), added by FDASIA, FDA will award priority review vouchers to sponsors of rare pediatric disease product applications that meet certain criteria. FDA has determined that VIMIZIM (elosulfase alfa), manufactured by BioMarin Pharmaceutical, Inc., meets the criteria for a priority review

voucher. VIMIZIM (elosulfase alfa) is indicated for the treatment of Mucopolysaccharidosis Type IV A (Morquio A syndrome). Morquio A syndrome is a rare congenital disorder caused by the absence or malfunctioning of an enzyme involved in an important metabolic pathway, leading to problems with bone development, growth, and movement.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.*

For further information about VIMIZIM (elosulfase alfa), go to the Drugs@FDA Web site at *http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.*

Dated: March 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05410 Filed 3–11–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: National Health Service Corps Ambassador Portal OMB No. 0915–xxxx—New.

Abstract: The National Health Service Corps (NHSC), administered by the Health Resources and Services Administration, is committed to improving the health of the nation's underserved by uniting communities in need with caring health professionals and by supporting communities' efforts to build better systems of care. The NHSC programs provide scholarships and repay educational loans for primary care physicians, dentists, nurse practitioners, physician assistants, behavioral health providers, and other primary care providers who agree to practice in areas of the country that need them most. The NHSC invites individuals who are affiliated with academic, clinical, trade, and other public health related organizations to apply to be volunteers within the NHSC Ambassador Program. NHSC Ambassadors are dedicated volunteers who help educate and inform prospective NHSC members. Ambassadors give their time and talents to spread the word about the opportunities available through the NHSC and serve as additional local resources for current NHSC members. NHSC Ambassadors inspire and motivate students and providers to provide primary health care in communities with limited access to care.

The NHSC Ambassador Portal will serve as both the application interface for interested individuals to apply and become NHSC Ambassadors, as well the public-facing online searchable database of Ambassador contact information. Applicants will create individual Ambassador profiles that will contain information such as name, email address(es), professional/employment information (including organization name and address or the school which they attend), phone number(s), which discipline of students and/or professionals they interact with, and a brief reason why they would like to be an Ambassador. Completed applications will be forwarded through the portal to NHSC staff for approval. If approved, the NHSC Ambassadors will have the opportunity to add brief professional biographies and social network addresses to their profile. Assistance in completing the application will be provided through prompts via the online portal and also through the NHSC Customer Care Center, if necessary.

Need and Proposed Use of the Information: The need and purpose of this information collection is to create a database where interested parties can search for NHSC Ambassadors (that meet specific search criteria) to serve as local resources on the NHSC programs. The other purpose is that NHSC can have access to volunteers who are available to spread important programmatic information on behalf of the NHSC.

Likely Respondents: Individuals who are affiliated with academic, clinical, trade, and other public health related organizations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.