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 sections 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, 2013, through September 30, 2013. 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, 2013, THROUGH SEPTEMBER 30, 2013

PMA No., Docket No.	Applicant	Trade name	Approval date
P120022, FDA–2013–M–0851	QIAGEN Manchester Ltd	*therascreen*® EGFR RGQ PCR Kit	July 12, 2013.
P110002, FDA–2013–M–0987	LDR Spine USA, Inc	Mobi-C® Cervical Disc Prosthesis	August 7, 2013.
P120009, FDA–2013–M–0988	PFM Medical AG	Nit-Occlud® PDA	August 16, 2013.
P120004, FDA–2013–M–1017	Parascript, LLC	Parascript® *Accu*Detect® 6.1.0	August 22, 2013.
P110009, FDA–2013–M–1095	LDR Spine USA, Inc	Mobi-C® Cervical Disc Prosthesis	August 23, 2013.
P110040, FDA–2013–M–1159	Medtronic Vascular	Medtronic Vascular Complete® SE Vascular Stent System.	September 19, 2013.
P120010, FDA–2013–M–1206	Medtronic, Inc	MiniMed 530G System	September 26, 2013.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: March 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05347 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–0253]

Methods for Thrombogenicity Testing; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Workshop on Methods for Thrombogenicity Testing.'' Planned topics of discussion include the optimization of in vitro and in vivo thrombogenicity test methods and the identification of alternative in vitro tests.

Date and Time: The public workshop will be held on April 14, 2014, from 9 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503, sections B and C), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Persons: Anchal Kaushiva, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1266, Silver Spring, MD 20993–0002, 301–796–6330, FAX: 301–847–8115, email: *anchal.kaushiva@fda.hhs.gov*, or James Kleinedler, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1102, Silver Spring, MD 20993–0002, 301–796–9448, FAX: 301–847–8115, email: *james.kleinedler@fda.hhs.gov.*

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by April 4, 2014, at 5 p.m., EST. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, 301–796–5661, email: *susan.monahan@fda.hhs.gov* no later than April 4, 2014.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* and select this public workshop from the posted events list. Please provide complete contact information for each attendee, including name, title, and affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by April 4, 2014, at 5 p.m. Early registration is recommended because

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