vote on information regarding a de novo request for the SEEKER Newborn Screening System (SEEKER System), by Baebies, Inc. The SEEKER System consists of the SEEKER Analyzer, the SEEKER 4-Plex Assay Kit, the SEEKER Cartridges, the Spot Logic software, and quality control materials; it uses digital microfluidic technology to measure multiple lysosomal enzymatic activities quantitatively from newborn dried blood spot specimens. The proposed Indication for Use for the SEEKER System device, as stated in the de novo request, is as follows:

The SEEKER System is intended for quantitative measurement of the activity of multiple lysosomal enzymes from newborn dried blood spot specimens. Reduced activity of these enzymes may be indicative of a lysosomal storage disorder. The enzymes measured using the SEEKER 4-Plex Assay Kit and their associated lysosomal storage disorder are listed in the following table.

Enzyme (abbreviation)	Disorder
α-L-iduronidase (IDUA)	Mucopolysaccharidosis Type I (MPS I) disease.
α-D-glucosidase (GAA)	Pompe disease.
β-glucocerebrosidase (GBA)	Gaucher disease.
α-D-galactosidase A (GLA)	Fabry disease.

Reduced activity for any of the four enzymes must be confirmed by other confirmatory diagnostic methods.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 3, 2016. On August 10, 2016, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 26, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 27, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at *AnnMarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 24, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–12658 Filed 5–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Sequencing Quality Control II; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Sequencing Quality Control II.'' The purpose of the public workshop is to define the scope of project and study designs, and solicit participation of DNA sequencing community and stakeholders for data generation, management, analysis, and interpretation.

DATES: The public workshop will be held on September 13 and 14, 2016, from 8 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at Wilson Hall, Bldg. 1, National Institutes of Health (NIH), 31 Center Dr., Bethesda, MD 20892. Entrance for the public workshop participants (non-NIH employees) is through the NIH Gateway Center where routine security check procedures will be performed. For parking and security information, please refer to *https://www.nih.gov/about-nih/visitor-information/campus-access-security.*

FOR FURTHER INFORMATION CONTACT: Weida Tong, National Center for Toxicological Research (NCTR), Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870–543–7142, FAX: 870–543–7854, *weida.tong@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA's Critical Path Initiative (*http://www.fda.gov/oc/initiatives/criticalpath/*) identifies pharmacogenomics as a key opportunity in advancing medical product development and personalized medicine. FDA has issued the ''Guidance for Industry: Pharmacogenomic Data Submissions'' (*http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079849.pdf*) to facilitate scientific progress in the field of pharmacogenomic data integration in drug development and medical diagnostics. Microarrays represent a core technology in

pharmacogenomics and toxicogenomics; however, next-generation sequencing technologies promise to provide some unique advantages in DNA and RNA analyses and are expected to be adopted by the pharmaceutical and medical industries for advancing personalized nutrition and medicine.

Starting in 2005, FDA initiated an open project, MicroArray Quality Control (MAQC), which has gone through three phases. MAQC–I focused on the technical aspects of microarray-based gene expression measurements, the MAQC–II focused on validation of microarray-based predictive models, and MAQC–III, which is also called the Sequencing Quality Control (SEQC), focused on assessing the performance of whole transcriptome sequencing (RNA-seq).

The Sequencing Quality Control Phase 2 (SEQC–II) is a natural extension of the SEQC project with emphasis on DNA-Seq for various applications. The SEQC–II project, with broad participation from scientists and reviewers within FDA and collaborators across the public, academic, and private sectors, is expected to help prepare FDA for the next wave of submission of genomic data generated from the next-generation sequencing technologies.

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by August 31, 2016. FDA will email a confirmation to those who have registered. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. No registration on the day of the public workshop will be provided.

If you need special accommodations due to a disability, please contact Weida Tong (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Dated: May 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12656 Filed 5–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on July 21 and July 22, 2016, from 8 a.m. to 6 p.m.

ADDRESSES: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 1116, 10903 New Hampshire Ave., Silver Spring, MD 20993; *patricio.garcia@fda.hhs.gov;* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On July 21, 2016, the committee will discuss, make recommendations, and vote on information regarding a premarket approval application (PMA) panel-track supplement for a proposed change in intended use of Dexcom, Inc.'s, Dexcom G5® Mobile Continuous Glucose Monitoring System (CGM) device so that, in addition to tracking and trending interstitial fluid glucose concentrations, patients can use the device as a replacement for their blood glucose meters and make treatment decisions based on the interstitial fluid glucose concentration reported by the CGM.

On July 22, 2016, the committee will discuss and make recommendations on information regarding a premarket notification (510(k)) submission for the Alere Afinion™ HbA1c Dx point-of-care test system, sponsored by Alere Technologies AS. The proposed intended use, as stated by the sponsor:

> Alere Afinion HbA1c Dx is an in vitro diagnostic test for quantitative determination of glycated hemoglobin (% hemoglobin A1c, HbA1c) in human whole blood. This test is to be used as an aid in the diagnosis of diabetes and as an aid in identifying patients who may be at risk for developing diabetes. The measurement of % HbA1c is recommended as a marker of long-term metabolic control in persons with diabetes mellitus. For use in clinical laboratories and point of care laboratory settings.

Current clinical guidelines contraindicate the use of point-of-care hemoglobin A1c (HbA1c) tests to diagnose diabetes. FDA is seeking feedback from the clinical community to determine significant, scientific and practical, reservations or support for using this point-of-care HbA1c test as an aid in the diagnosis of diabetes and pre-diabetes.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 15, 2016. Oral presentations from the public will be scheduled on July 21 and 22, 2016, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 7, 2016. Time allotted for each presentation may be limited. If the