approved under OMB control number 0910–0485. The latex allergy caution required by 21 CFR 801.437 and referenced in the guidance does not constitute a ''collection of information'' under the PRA. Rather, it is a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public.'' (5 CFR 1320.3(c)(2)).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30586 Filed 12–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0644]

SEQC—The Sequencing Quality Control Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of solicitation.

SUMMARY: The Food and Drug Administration (FDA) is soliciting volunteers to participate in the SEQC (Sequencing Quality Control) project to objectively assess the technical performance of different next-generation sequencing technologies in DNA (deoxyribonucleic acid) and RNA (ribonucleic acid) analyses and to evaluate the advantages and limitations of various bioinformatics solutions in handling and analyzing the massive new data sets. The SEQC project is a natural extension of the MicroArray Quality Control (MAQC) project (*http://www.fda.gov/nctr/science/centers/toxicoinformatics/maqc/*) and is being coordinated by the FDA. This project is open to the public. Vendors of next-generation sequencing technologies and institutions interested in the generation, management, analysis, and interpretation of the resulting sequence data are welcome to participate.

DATES: Requests to participate in the SEQC project at the National Center for Toxicological Research (NCTR) should be submitted on or before 4:30 p.m., CST, January 9, 2009, or be postmarked on or before January 9, 2009.

ADDRESSES: Requests to participate in the SEQC project should be sent to Leming Shi, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870–543–7387, FAX: 870–543–7854; e-mail: *leming.shi@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/cder/guidance/6400fnl.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.

The SEQC 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.

Dated: December 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30410 Filed 12–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict Panel for BGES and BMRD.

Date: January 7, 2009.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Scott Osborne, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, MD 20892, (301) 435–1782, *osbornes@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, IMM Member Application Review.

Date: January 9, 2009.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Cathleen L. Cooper, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4208, MSC 7812, Bethesda, MD 20892, 301–435–3566, *cooperc@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Epidemiology of Chronic and Acute Outcomes.

Date: January 15, 2009.

Time: 10:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.