Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21158 Filed 10–21–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

MicroArray Quality Control Project Meeting on MicroArray Quality Control; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''MicroArray Quality Control (MAQC) Project Meeting on MicroArray Quality Control.'' The focus of the 2-day meeting will be to review the datasets generated by the MAQC study.

Date and Time: The meeting will be held on Thursday, December 1, 2005, from 8 a.m. to 5 p.m. and Friday, December 2, 2005, from 8 a.m. to 2 p.m.

Location: The meeting will be held at the Crowne Plaza Cabana Portofino Room on December 1, 2005, and the St. Tropez Room on December 2, 2005, 4290 El Camino Real, Palo Alto, CA 94306, 650–857–0787, FAX: 650–496–1939, Web site: *http://www.cppaloalto.crowneplaza.com/*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Contact: Leming Shi, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870–543–7387, FAX: 870–543–7686, e-mail: *leming.shi@fda.hhs.gov*.

Registration: There will be no registration fee for attending the meeting. However, interested parties should send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person (see *Contact*) at least 15 days in advance of the meeting. Participants are responsible for their own costs of travel, lodging, and meals.

FDA welcomes the attendance of the public at this meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jeannette Coleman at 870–543–7087, e-mail: *jeanette.coleman@fda.hhs.gov*, at least 7 days in advance of the meeting.

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 issued the ''Guidance for Industry: Pharmacogenomic Data Submissions'' (*http://www.fda.gov/cder/guidance/6400fnl.pdf*) to facilitate scientific progress in the field of pharmacogenomics and to facilitate the use of pharmacogenomic data in drug development and medical diagnostics. A microarray is a tool for analyzing gene expression that consists of a small membrane or glass slide containing samples of many genes arranged in a regular pattern. Microarrays represent a core technology in pharmacogenomics; however, before this technology can successfully and reliably be applied in clinical practice and regulatory decisionmaking, standards and quality measures need to be developed.

The MAQC project involves six FDA centers, major providers of microarray platforms and ribonucleic acid (RNA) samples, government agencies, academic laboratories, and other stakeholders. The MAQC project aims to evaluate quality control metrics and thresholds for objectively assessing the performance achievable by various microarray platforms, and evaluating the advantages and disadvantages of various data analysis methods. Two RNA samples will be selected for three species (i.e., human, rat, and mouse), and differential gene expression levels between the two samples will be calibrated with microarrays and other technologies (e.g., quantitative real time-polymerase chain reaction (qRT–PCR)). The resulting microarray datasets will be used for assessing the precision and crossplatform/laboratory comparability of microarrays, and the qRT–PCR datasets will enable evaluation of the nature and magnitude of any systematic biases that may exist between microarrays and qRT–PCR. The availability of the calibrated RNA samples and the resulting microarray and qRT–PCR datasets, which will be made readily accessible to the microarray community, will allow individual laboratories to identify and correct procedural failures more easily. The MAQC project will help improve the microarray technology and foster its proper applications in discovery, development and review of FDA-regulated products. For more information about the MAQC project, please visit *http://www.fda.gov/nctr/science/centers/toxicoinformatics/maqc/*.

At the public meeting, each participating platform provider will give a 15-minute presentation to summarize the datasets generated by its test sites and to describe its analysis results. Each analysis site will also give a 15-minute presentation on its analysis results. Other interested parties may present data, information, or views, orally or in writing, on issues related to microarray quality control and data analysis. Those desiring to make formal oral presentations should notify the contact person (see *Contact*) before November 4, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present with an indication of the approximate time requested to make the presentation.

Dated: October 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–21152 Filed 10–21–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Injuries Among Youth With Developmental Disabilities

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 Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Injuries Among Youth with Developmental Disabilities. *Type of Information Collection Request:* New. *Use of Information:* The proposed study seeks (1) to determine if children with disabilities are at increased risk of injury compared to typically developing children, and (2) to identify which injuries children with developmental disabilities are at particular risk of sustaining. Existing data on this topic are scarce and equivocal. Results will help inform prevention efforts. NICHD proposes to collect information about disabilities among children with injuries through phone interviews with

parents/guardians of children who were seen in an emergency department for an injury. This information will be collected in conjunction with the Consumer Product Safety Commission's (CPSC's) National Electronic Injury Surveillance System (NEISS). The NEISS is part of CPSC's routine data collection. Through this system, trained abstractors code information from all injury-related emergency department visits in the participating hospital. Additional information will be collected through ''follow-back'' phone interviews with parents/guardians of injured children seen in participating hospitals. NICHD will collect information on developmental disabilities among injured children e.g., cerebral palsy, blindness, deafness or trouble hearing, autism, and mental retardation), medical/psychological conditions e.g. epilepsy/seizures, ADHD), medication use, and other potential risk factors for injury including family structure, sibling characteristics, and caregiver supervision practices. Finally, NICHD would like to determine if typically developing children who have a sibling with a developmental disability, who may compete for supervisory time, are at a greater risk of injury than other children. This Interagency Agreement provides funds from NICHD to CPSC to complete 8000 telephone interviews with parents/guardians of injured children. The sample of interviewees will be derived from a larger sample of children who will be systematically selected from the NEISS system. Sampling will cover an entire year to account for seasonal variations in injury rates. Two thousand interviews will be conducted in 4 different age groups: 0–4 years, 5–9 years, 10–14 years, and 15–19 years. Intentional injuries will not be included in the sampling pool. Further, deaths and hospitalizations will be excluded. Interviews will be limited to those who can complete an interview in English or Spanish. *Frequency of Response:* One interview; *Affected Public:* Individuals or households; *Type of Respondents:* Parents or Guardians; The annual reporting burden is as follows: *Estimated Number of Respondents:* 8000. *Estimated Number of Responses per Respondent:* 1; Average Burden Hours Per Response 0.33; and *Estimated Total Annual Burden Hours Requested:* 2640. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Type of respondents	Estimated numbers of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Parents/guardians	8000	1	.33	2640

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Gitanjali Saluja, Ph.D., 6100 Executive Blvd. Suite 7B03, Rockville, MD 20852. Phone: 301–435–6917. E-mail: *salujag@mail.nih.gov*

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 13, 2005.

Paul L. Johnson,

Project Clearance Liaison, NICHD, National Institutes of Health.

[FR Doc. 05–21116 Filed 10–21–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

NIH3T3 Cell Lines Carrying c-Met Mutations Including G3906A, G3522A, G3810T, T3936C, T3936G, T3997C, C3528T, C3564G, C3831G, A3529T, and T3640C

Laura S. Schmidt (NCI).

HHS Reference No. E–327–2005/0—Research Tool.

Licensing Contact: John Stansberry; 301/435–5236: *stansbej@mail.nih.gov*.

MET is over expressed in a variety of cancers including hereditary papillary renal cell carcinoma and non-small cell lung cancer. These cell lines carry naturally-occurring Met mutations and were derived from the germline of patients with hereditary papillary renal cell carcinoma. These cell lines can be used as drug discovery research reagents.

These cell lines were described in part in Schmidt et al., ''Novel mutations of the MET proto-oncogene in papillary renal carcinomas. Oncogene. (1999) 18:2343–2350 and Jeffers et al., ''Activating mutations for the met tyrosine kinase receptor in human cancer.'' PNAS (1997) 94:11445–11450.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.