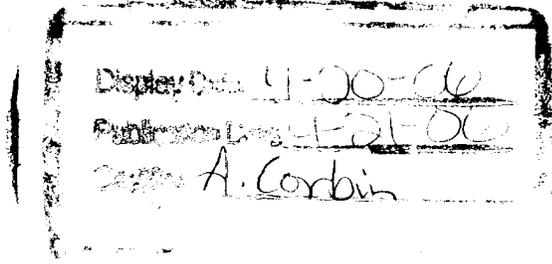


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration



MicroArray Quality Control Project on the Evaluation of Analysis Protocols for Deoxyribonucleic Acid Microarray Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of solicitation.

SUMMARY: The Food and Drug Administration (FDA) is soliciting gene expression datasets from deoxyribonucleic acid (DNA) microarray studies, as well as proposals to analyze these datasets in order to evaluate the impact of different analysis protocols on the selection of genes and their associated signatures for biomarker pattern development. This project is being coordinated by FDA as a followup to the MicroArray Quality Control (MAQC) Project. This evaluation process is open to the public.

DATES: Datasets and proposals for participation in the project must be received by the National Center for Toxicological Research on or before 4:30 p.m. c.s.t. on May 31, 2006, or be postmarked on or before May 31, 2006.

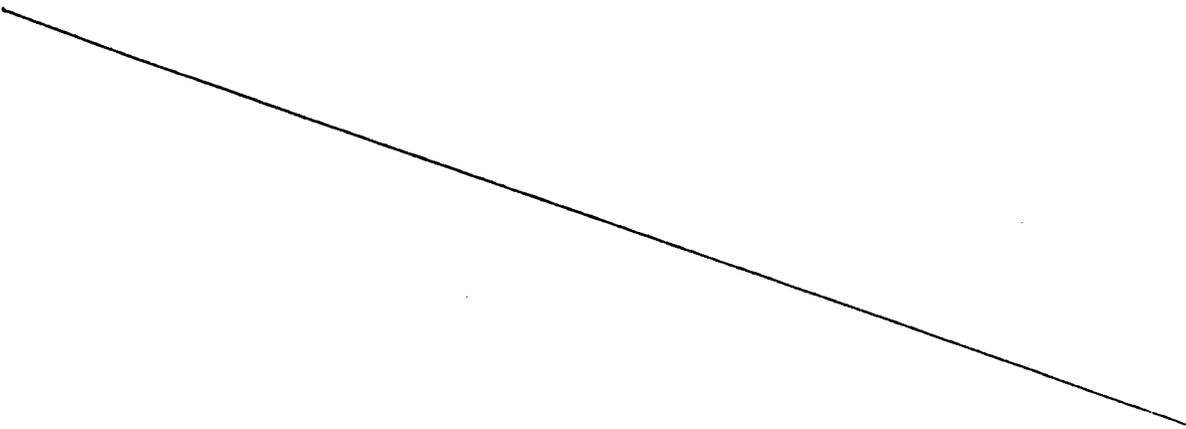
ADDRESSES: Datasets and proposals should be sent to Leming Shi, National Center for Toxicological Research, Food and Drug Administration, 3900 NCTR Rd., Jefferson, AR 72079, 870-543-7387, FAX: 870-543-7686; e-mail: leming.shi@fda.hhs.gov.

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 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.

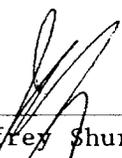
A microarray is a tool for analyzing gene expression. It consists of a small membrane or glass slide containing samples of many genes arranged in a regular pattern. DNA is a nucleic acid—usually in the form of a double helix—that contains the genetic instructions specifying the biological development of all cellular forms of life and most viruses. DNA microarray is a collection of microscopic DNA spots attached to a solid surface, such as glass, plastic or silicon chip forming an array. DNA microarrays represent a core technology in pharmacogenomics and toxicogenomics; however, before this technology can be reliably applied in clinical practice and regulatory decisionmaking, further evaluation is needed of the process for the analysis of hybridization data that results in predictive signatures.

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 will work with participating scientists to develop baseline practices for the analysis of hybridization data. Original datasets, analyses, and conclusions from this project will be made available to the public throughout the project.



For more information about the MAQC project, please visit <http://www.fda.gov/nctr/science/centers/toxicoinformatics/maqc/>.

Dated: 4/13/06
April 13, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S

