44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Pharmacogenomic Data Submissions (OMB Control Number 0910–0557—Extension)

The guidance provides recommendations to sponsors submitting or holding INDs, NDAs, or BLAs on what pharmacogenomic data should be submitted to the agency during the drug development process. Sponsors holding and applicants submitting INDs, NDAs, or BLAs are subject to FDA requirements for submitting to the agency data relevant to drug safety and efficacy (§§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12).

The guidance interprets FDA regulations for IND, NDA, or BLA submissions, clarifying when the regulations require pharmacogenomics data to be submitted and when the submission of such data is voluntary. The pharmacogenomic data submissions described in the guidance that are required to be submitted to an IND, NDA, BLA, or annual report are covered by the information collection requirements under parts 312, 314, and 601 (21 CFR parts 312, 314, and 601) and are approved by OMB under control numbers 0910–0014 (part 312—INDs); 0910–0001 (part 314—NDAs and annual reports); and 0910–0338 (part 601—BLAs).

The guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decision-making, and other, less well-developed exploratory tests. The submission of exploratory pharmacogenomic data is not required under the regulations, although the agency encourages the voluntary submission of such data.

The guidance describes the voluntary genomic data submission (VGDS) that can be used for such a voluntary submission. The guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated as a VGDS. The data submitted in a VGDS and the level of detail should be sufficient for FDA to be able to interpret the information and independently analyze the data, verify results, and explore possible genotype-phenotype correlations across studies. FDA does not want the VGDS to be overly burdensome and time-consuming for the sponsor.

FDA has estimated the burden of preparing a voluntary submission described in the guidance that should be designated as a VGDS. Based on FDA's experience with this guidance over the past few years, and on FDA's familiarity with sponsors' interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately seven sponsors will submit approximately one VGDS and that, on average, each VGDS will take approximately 50 hours to prepare and submit to FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Voluntary Genomic Data Submissions Total	7	1	7	50	350

[1] There are no capital costs or operating and maintenance costs associated with this collection.

Dated: October 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–27847 Filed 11–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0381]

Generic Drug User Fee; Notice of Public Meeting; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until December 6, 2010, the comment period for the notice of public meeting entitled Generic Drug User Fee; Public Meeting; Request for Comments, published in the **Federal Register** of August 9, 2010 (75 FR 47820). In that notice, FDA announced a public meeting that took place on September 17, 2010, to gather stakeholder input on the development of a generic drug user fee program. FDA is reopening the comment period to permit public consideration of late-received comments and to provide an opportunity for all interested parties to provide information and share views on the matter.

DATES: Submit either electronic or written comments by December 6, 2010.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4238, Silver Spring, MD 20993–0002, 301–796–4830, Fax: 301–847–3541, E-mail: *peter.beckerman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 9, 2010 (75 FR 47820), FDA published a notice of a public meeting on the development of a generic drug user fee program. In that notice, FDA posed several questions related to a user fee for human generic drugs, and sought public input on such a program. The Agency received submissions and presentations from the public meeting, which are now posted on FDA's Web site. Some submissions arrived after the formal closing of the docket and FDA has decided to reopen the docket to permit public input on all the submissions.

Interested persons were originally given until October 17, 2010, to comment on the development of a generic drug user fee program. FDA is now reopening the docket to permit comment until December 6, 2010.

II. Request for Comments

Following publication of the August 9, 2010, meeting notice and request for comment, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period of 30 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues. In light of this request, and the arrival of late submitted comments, FDA is reopening the comment period for an additional 30 days.

III. How To Submit Comments

Regardless of attendance at the public meeting, interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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., Monday through Friday.

Dated: October 29, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–27824 Filed 11–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

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.

System for Magnetic Resonance Spectroscopy of Brain Tissue for Pattern-Based Diagnostics

Description of Invention: Available for licensing and commercial development is a system for preprocessing magnetic resonance spectroscopy (MRS) data of brain tissue for pattern-based diagnostics. The MRS preprocessing system includes an MRS preprocessing module that executes an operation that normalizes MRS spectrum data, recalibrates and scales the normalized MRS spectrum data, and then renormalizes the scaled MRS spectrum data. The resulting preprocessed MRS data is used to assist in identifying abnormalities in tissues shown in MRS scans. Raw MRS spectrum data and scaling the raw MRS spectrum data is achieved by a plurality of weighting constants to generate a preprocessed MRS spectrum data. The method may also include providing raw MRS spectrum data, recalibrating the raw MRS spectrum data, and scaling the recalibrated MRS spectrum data by using a plurality of weighting constants to generate a preprocessed MRS spectrum data.

Applications

- MRI Imaging.
- Brain Imaging.
- Neurology.

Inventors: Jon G. Wilkes (FDA/NCTR), Dan A. Buzatu (FDA/NCTR), Pierre Alusta (FDA/NCTR), Bruce A. Pearce (FDA/NCTR), Richard Beger (FDA/NCTR), Inessa Im (FDA/NCTR).

Patent Status: U.S. Provisional Application No. 61/261,170 filed 13 Nov 2009 (HHS Reference No. E–298–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The FDA National Center for Toxicological Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize FDA's magnetic resonance spectroscopy technology in various imaging and diagnostic applications. Please contact Alice Y. Welch, PhD at 301–796–8449 or *alice.welch@fda.hhs.gov* for more information.

Cancer-Linked Sequences Encoding the A2BP1/FOX1 Gene

Description of Invention: Mesothelioma is a rare type of cancer in which malignant cells are found in the lining of the chest or abdomen. Symptoms are frequently misdiagnosed and an accurate diagnosis generally does not occur until advanced stages, and patients live on average nine to thirteen months after an accurate diagnosis. To date, there are no effective systemic treatments.

Researchers at the National Cancer Institute, NIH, have identified a recurrent alteration in the DNA sequence for ataxin-2 binding protein (A2BP1/FOX1) in human mesothelioma and colorectal cancers that is present in at least twenty percent (20%) of cancer cell lines and primary tumor samples. The sequence is not present in normal tissue, proving that it has arisen as an acquired somatic mutation in cancer. Furthermore, additional data suggests a possible role for the alteration in neurological diseases such as autism,