

Human Services, is conducting the project entitled "Building Strong Families Demonstration and Evaluation." The purpose of the project is to determine whether well-designed interventions can help low-income, unwed parents who are interested in marriage, fulfill their aspirations for a healthy marriage and strong family. The project plan includes obtaining information from focus groups of low-income men and women who have had a child out-of-wedlock. Information from the focus groups will provide a better understanding of the needs and interests of these men and women and aid in the design of interventions that address those needs and interests. At a

later stage, the project will assess the net impact of interventions with couples beginning round the time of the birth of their child.

Focus groups participants' input will be sought to help design programs to help interested couples strengthen their relationship, achieve a healthy marriage if that is the path they choose, and thus, enhance child and family well-being. It is expected that programs will be designed around two main components. First, the programs will provide instruction in the skills and knowledge that research has shown to be associated with increased quality and stability in relationships and marriage. This focus is the distinctive component of the

Building Strong Families Demonstration and Evaluation. In addition, programs to be tested will help couples access other services that they may need to sustain a healthy relationship and marriage (e.g., mental health services, employment services).

Respondents: The respondents for the Focus Group Protocols and information sheets are to be low-income, unmarried, expectant or recent parents and newly married couples with children who volunteer to participate. The attendance goal for each group is 8 to 12 people. Approximately 26 focus groups are expected to be convened for a total of 208 to 312 respondents.

Annual Burden Estimates:

TABLE 1.—ESTIMATES OF ANNUALIZED BURDEN HOURS

| Data collection instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|----------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Focus Group Protocol | 312 | 1 | 1.5 | 468.0 |
| Information Sheet | 312 | 1 | 0.1 | 31.2 |
| Total | | | 1.6 | 499.2 |

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: rsargis@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF, E-mail address: lauren_wittenberg@omb.eop.gov.

Dated: October 28, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03-27614 Filed 11-3-03; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0497]

Draft Guidance for Industry on Pharmacogenomic Data Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Pharmacogenomic Data Submissions." The draft guidance provides recommendations to sponsors holding investigational new drug applications (INDs), new drug applications (NDAs), and biologics license applications (BLAs) on what pharmacogenomic data to submit to the agency during the drug development process, the format of submissions, and how the data will be used in regulatory decisionmaking. The draft guidance is intended to facilitate scientific progress in the area of pharmacogenomics, which should enable the FDA to use pharmacogenomic data in regulatory policies and decision making.

DATES: Submit written or electronic comments on the draft guidance by February 2, 2004. General comments on agency guidance documents are welcome at any time. Submit written or

electronic comments on the collection of information by January 5, 2004.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance and on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance and the collection of information to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Lawrence Lesko, Center for Drug Evaluation and Research (HFD-850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5690, or

Raj Puri, Center for Biologics Evaluation and Research (HFM-735),

Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0471.

SUPPLEMENTARY INFORMATION:

I. Background

Although the field of pharmacogenomics is in its infancy, the promise of pharmacogenomics lies in its potential to predict sources of interindividual variability in drug response (both efficacy and toxicity), thus allowing individualization of therapy to maximize effectiveness and minimize risk. Pharmaceutical sponsors have been reluctant to embark on programs of pharmacogenomic testing during the FDA-regulated phases of drug development, due to uncertainties in how FDA will react to the data being generated.

To facilitate scientific progress in the area of pharmacogenomics, FDA is announcing the availability of a draft guidance for industry entitled “Pharmacogenomic Data Submissions.” The draft guidance provides recommendations to sponsors holding INDs, NDAs, and BLAs on what pharmacogenomic data to submit to the agency during the drug development process, the format of submissions, and how the data will be used in regulatory decisionmaking. The draft guidance is also intended to facilitate the agency’s use of such data during regulatory decisionmaking.

Sponsors submitting or holding 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 (21 CFR 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12)). These regulations were developed before the advent of widespread animal or human genetic or gene expression testing. FDA has received numerous inquiries about how sponsors who are conducting such testing can comply with the regulations. From a public policy perspective, a number of factors should be considered when interpreting how these regulations should apply to the developing field of pharmacogenomics. This draft guidance discusses these factors as well as the content and possible formats for submitting pharmacogenomic data to the agency in INDs, NDAs, and BLAs and how FDA expects to use the data in regulatory decisionmaking.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on the draft guidance. Two

copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 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 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 on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Pharmacogenomic Data Submissions.

Description: The draft 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).

Description of Respondents: Sponsors submitting or holding INDs, NDAs, and BLAs for human drugs and biologics.

Burden Estimate: The draft 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 draft 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; approved until January 1, 2006); 0910–0001 (part 314—NDAs and annual reports; approved until March 31, 2005); and 0910–0338 (approved until August 31, 2005).

The draft guidance distinguishes between pharmacogenomic tests that may be considered valid biomarkers appropriate for regulatory decisionmaking, 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 draft guidance describes the Voluntary Genomic Data Submission (VGDS) that can be used for such a voluntary submission. The draft guidance does not recommend a specific format for the VGDS, except that such a voluntary submission be designated 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 is requesting public comments on the following estimates of the burden of preparing a voluntary submission described in the draft guidance that should be designated as a VGDS. Based on FDA’s familiarity with sponsors’ interest in submitting pharmacogenomic data during the drug development process, FDA estimates that approximately 20 sponsors will submit approximately 80 VGDSs and that, on average, each VGDS will take approximately 10 hours to prepare and submit to FDA.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Hours per Response | Total Hours |
|--------------------------|--------------------|---------------------------------|------------------------|--------------------|-------------|
| Genomic Data Submissions | 20 | 4 | 80 | 10 | 800 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-27646 Filed 11-3-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

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 meeting.

The meeting 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: National Eye Institute Special Emphasis Panel, Clinical Topic: U10, R21, R03, Data, R01, K23s".

Date: November 10, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Radisson Old Town Alexandria, 901 Fairfax Street, Alexandria, VA 22314.

Contact Person: Jeanette M Hosseini, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, Bethesda, MD 20892, (301) 451-2020.

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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: October 29, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-27710 Filed 11-3-03; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

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 meeting.

The meeting 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: National Eye Institute Special Emphasis Panel, Retinal Clinical Applications Section II.

Date: December 3, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Hwy, Arlington, VA 22202.

Contact Person: Jeanette M Hosseini, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, Bethesda, MD 20892, (301) 451-2020.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: October 29, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-27711 Filed 11-3-03; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

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 meeting.

The meeting 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: National Institute of General Medical Sciences Special Emphasis Panel, Predoctoral Research Training Grant.

Date: November 4-5, 2003.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Laura K. Moen, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN-12, Bethesda, MD 20892, 301-594-3998, moenl@nigms.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 29, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-27702 Filed 11-3-03; 8:45 am]

BILLING CODE 4140-01-M