

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 Information 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.

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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 (HFM-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),