this reason, the following changes are being proposed to the current form:

1. The expenditures columns will be reordered so that when reading left to right, the three types of funding that sum to total expenditures—SSBG allocation, funds transferred into SSBG, and expenditures of all other Federal, State, and local funds—are listed prior to total expenditures.
2. A space will be added, and referenced in item 29, where States can report more detail about other services. This added information will help to define the specific services funded under this service category.
3. The column for total adults will be removed. A new column, ''Adults of Unknown Age'' will be added. The three age groups of adults—''Adults Age 59 and younger,'' ''Adults Age 60 and older,'' and ''Adults of Unknown Age''—should equal the total number of adults.
4. The recipients columns will be reordered so that when reading left to right, the four ages of recipients—children, adults age 59 and younger, adults age 60 and older, and adults of unknown age—are listed prior to total recipients.

The SSBG program provides funds to assist States in delivering social services directed toward the needs of children and adults in each State. Funds are allocated to the States in proportion to their populations. States, including the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Northern Mariana Islands, and American Samoa, have substantial discretion in their use of funds and may determine what services will be provided, who will be eligible, and how funds will be distributed among the various services. State or local SSBG agencies (*i.e.,* county, city, or regional offices) may provide the services or may purchase them from qualified agencies, organizations, or individuals. States report as recipients of SSBG-funded services any individuals who receive a service funded at least partially by SSBG.

States are required to report their annual SSBG expenditures on a standard postexpenditure report, which includes a yearly total of adults and children served and annual expenditures in each of 29 service categories. Reporting requirements for SSBG were originally described in the Federal Register, Volume 58, Number 218, on Monday, November 15, 1993. The report is due either 6 months after the end of the reporting period or at the time the State submits the preexpenditure report for the reporting period beginning after that 6 month period. The report must address: (1) The number of individuals (as well as number of children and number of adults) who receive services paid for in whole or in part with Federal funds under the Social Services Block Grant; (2) The amount of Social Services Block Grant funds spent in providing each service; (3) The total amount of Federal, State, and local funds spent in providing each service, including Social Services Block Grant funds; and (4) The method(s) by which each service is provided, showing separately the services provided by public agencies and private agencies.

Information collected on the postexpenditure report is analyzed and described in an annual report on SSBG expenditures and recipients produced by the Office of Community Services. The information contained in this report is used to establish how SSBG funding is used for the provision of services in each State to each of many specific populations of needy individuals.

Respondents: This report is completed once annually by a representative of the agency that administers the Social Services Block Grant at the State level in each State, the District of Columbia, and the Territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Postexpenditure Report	56	1	110	6,160

Estimated Total Annual Burden Hours: 6,160.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20477, Attn: ACF Reports Clearance Officer. E-mail address:*grjohnson@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 26, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–24349 Filed 10–29–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0459]

Draft Guidance for Industry on Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling

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 ''Draft Guidance for Industry on Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling.'' This guidance discusses agency recommendations on issues to consider when designing and

conducting pharmacokinetic (PK) studies in pregnant women and, specifically, on how to assess the influence of pregnancy on the PKs, and where appropriate, the pharmacodynamics (PD) of drugs or biologic products. The goals of this guidance are to recommend a framework for designing and conducting PK studies in pregnant women and stimulate further study and research to assist in rational therapeutics for pregnant patients.

DATES: Submit written or electronic comments on the draft guidance by January 3, 2005. General comments on agency guidance documents are welcome at any time.

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 Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kathleen Uhl, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5157.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Draft Guidance for Industry on Pharmacokinetics in Pregnancy—Study Design, Data Analysis, and Impact on Dosing and Labeling.'' This guidance is intended to provide recommendations to sponsors and investigators on how to design, conduct, and assess studies investigating the influence of pregnancy on the pharmacokinetics, and where appropriate, the pharmacodynamics of drugs or biologic products. During the clinical development of most products, pregnant women are actively excluded from trials, and, if pregnancy does occur during a trial, the usual procedure is to discontinue treatment and drop the patient from the study. Consequently, at the time of a drug's initial marketing, except for products developed to treat conditions specific to pregnancy, there are seldom meaningful human data on the appropriate dosage and frequency of administration during pregnancy. Even after years of marketing, data in product labels regarding PK and dose adjustments during pregnancy rarely provide more information for appropriate prescribing in pregnancy than what was available at the time of initial marketing.

The information in this guidance is intended to promote an increase in the amount of useful data concerning how drug kinetics are affected by pregnancy and to further encourage the development of appropriate therapeutic treatments for pregnant women. Topics covered include ethical considerations associated with conducting PK studies in pregnant women, study design, data analysis, labeling, and considerations for future research. The agency recommends using this guidance in conjunction with other pharmacological and clinical literature on the design, conduct, and interpretation of PK studies. Because the conduct of studies in pregnant women requires specialized knowledge in a variety of areas, investigators designing such studies are encouraged to obtain advice from experts in fields such as obstetrics, pediatrics, pharmacology, clinical pharmacology, pharmacometrics, statistics, and other applicable disciplines.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

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. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24308 Filed 10–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Funding Opportunity Title: Historically Black Colleges and Universities National Resource Center for Substance Abuse and Mental Health Service System Infrastructure Development (Short Title: HBCU–NRC)

Announcement Type: Initial.

Funding Opportunity Number: TI 05–002.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

DATES: *Due Date for Applications:* January 18, 2005.

(**Note:** Letters from State Single Point of Contact (SPOC) in response to E.O. 12372 are due March 21, 2005.)

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) and Center for Mental Health Services (CMHS), announce the availability of FY 2005 funds for a Historically Black Colleges and Universities National Resource Center (HBCU–NRC) for Substance Abuse and Mental Health Service System Infrastructure Development. A synopsis of this Notice of Funding Availability (NOFA), as well as many other Federal government funding opportunities, are also available at the Internet site: *http://www.grants.gov.*

For complete instructions, potential applicants must obtain a copy of SAMHSA's standard Infrastructure Grants Program Announcement, INF–05 PA, and the PHS 5161–1 (Rev. 7/00) application form before preparing and submitting an application. The INF–05 PA describes the general program design and provides instructions for applying for all SAMHSA Infrastructure Grants, including the Historically Black Colleges and Universities National Resource Center for Substance Abuse and Mental Health Service System Infrastructure Development. SAMHSA's Infrastructure Grants provide funds to