Maryland 21244–1850, Telephone Number: (410) 786–9493.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager, who will require the system name, the subject individual's name (woman's maiden name, if applicable), address, date of correspondence and control number.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5 (a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

CMS will receive CYPERS data periodically from CMS-approved cytology proficiency testing programs only. This System of Records protects the data transmitted by CMS-approved cytology proficiency testing programs at all stages of collection, manipulation, transmissions, storage, and maintenance, at the PT program and at CMS.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–836 Filed 1–13–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Follow-up to the National Survey of Child and Adolescent Well-Being.

OMB No.: 0970–0202.

Description: The Department of Health and Human Services intends to collect data on a subset of children and families who have participated in the National Survey of Child and Adolescent Well-Being (NSCAW). The NSCAW was authorized under Section 427 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. The Survey began in November 1999 with a national Sample of 5,501 children ages 0–14 who had been the subject of investigation by Child Protective Services (CPS) during the baseline data collection period, which extended from November 1999 through April 2000. Direct assessments and interviews were conducted with the children themselves, their primary caregivers, their caseworkers, and, for school-aged children, their teachers.

Follow-up data collections were conducted 12 months, 18 months and 36 months post-baseline. The current data collection plan involves only a subset of 1,497 children from the original sample, that is, children who were ages 0–12 months during the baseline period. The original sample design for NSCAW was stratified to include an over-sample or infants; thus, the subset that is the subject of this data collection is a representative sample of infants who were the targets of CPS investigations during the survey's baseline data collection period. This group will be at the beginning of their formal schooling as the next data collection begins, and will allow for the identification of early risk and protective factors, as well as the influence of services and service systems, on their functioning as they enter this critical transition period.

The NSCAW is unique in that it is the only source of nationally representative, firsthand information about the functioning and well-being, service needs and service utilization of children and families who come to the attention of the child welfare system. Information is collected about children's cognitive, social, emotional, behavioral and adaptive functioning, as well as family and community factors that are likely to influence their functioning. Family service needs and service utilization also are addressed in the data collection. The data collection for the follow-up will follow the same format as that used in previous rounds of data collection, and will employ the instruments that have been used with 5- to 7-year-olds in previous rounds. Data from NSCAW are made available to the research community through licensing arrangements from the National Data Archive on Child Abuse and Neglect, housed at Cornell University.

Respondents: Children, who are clients of the child welfare system, their primary caregivers, caseworkers, and teachers.

ANNUAL BURDEN ESTIMATES

Instrument	No. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours
Child Interview	1,497	1	1.2	1,796
Permanent Caregiver Interview	1,122	1	2.0	2,244
Foster Caregiver Interview	375	1	1.5	563
Caseworker Interview	375	1	1.0	375
Teacher Questionnaire	1,497	1	.75	1,123
Estimated Total Annual Burden Hours:				6,101

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 collections 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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, 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: January 10, 2005.

Robert Sargis,

Reports Clearance, Officer.

[FR Doc. 05–826 Filed 1–13–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Studies of Safety and Effectiveness of Orphan Products; Availability of Grants; Request for Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA) is announcing changes to its Office of Orphan Products Development (OPD) grant program for fiscal year (FY) 2006. This announcement supercedes the previous announcement of this program, which was published in the **Federal Register** of August 8, 2003 (68 FR 47340). Please note that there are new submission requests and requirements for this grant program. These include, but are not limited to, a requested letter of intent, a change in funding levels, a change in number of receipt dates, and changes in review criteria.

1. Background

The OPD was created to identify and promote the development of orphan products. Orphan products are drugs, biologics, medical devices, and foods for medical purposes that are indicated for a rare disease or condition (that is, one with a prevalence, not incidence, of fewer than 200,000 people in the United States). Diagnostic tests and vaccines will qualify only if the U.S. population of intended use is fewer than 200,000 people a year.

2. Program Research Goals

The goal of FDA's OPD grant program is to support the clinical development of products for use in rare diseases or conditions where no current therapy exists or where the product will improve the existing therapy. FDA provides grants for clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products. Applicants must include in the application's ''Background and Significance'' section an explanation of how the proposed study will either help gain product approval or provide essential data needed for product development. All funded studies are subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 *et seq.*) and regulations issued under it.

II. Award Information

Except for applications for studies of medical foods that do not need premarket approval, FDA will only award grants to support premarket clinical studies to determine safety and effectiveness for approval under section 505, 512, or 515 of the act (21 U.S.C. 355, 360b, or 360e*et seq.*) or safety, purity, and potency for licensing under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262).

FDA will support the clinical studies covered by this notice under the authority of section 301 of the PHS Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance, No. 93.103.

Applicants for Public Health Service (PHS) clinical research grants are encouraged to include minorities and women in study populations so research findings can be of benefit to all people at risk of the disease or condition under study. It is recommended that applicants place special emphasis on including minorities and women in studies of diseases, disorders, and conditions that disproportionately affect them. This policy applies to research subjects of all ages. If women or minorities are excluded or poorly represented in clinical research, the applicant should provide a clear and compelling rationale that shows inclusion is inappropriate.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national effort designed to reduce morbidity and mortality and to improve quality of life. Applicants may obtain a paper copy of the ''Healthy People 2010'' objectives, vols. I and II, for $70 ($87.50 foreign) S/N 017–000–00550–9, by writing to the Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Telephone orders can be placed to 202–512–2250. The document is also available in CD–ROM format, S/N 017–001–00549–5 for $19 ($23.50 foreign) as well as on the Internet at *http://www.healthypeople.gov/*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). Internet viewers should proceed to ''Publications.''

1. Award Instrument

Support will be in the form of a grant. All awards will be subject to all policies and requirements that govern the research grant programs of the PHS, including the provisions of 42 CFR part 52 and 45 CFR parts 74 and 92. The regulations issued under Executive Order 12372 do not apply to this program. The National Institutes of Health (NIH) modular grant program does not apply to this FDA grant program. All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 512, and 515 of the act, section 351 of the PHS Act, and regulations issued under any of these sections.

2. Award Amount

Of the estimated fiscal year (FY 2006) funding ($13.2 million), approximately $9.2 million will fund noncompeting continuation awards, and approximately $4 million will fund 10 to 12 new awards subject to availability of funds. The expected start date for the FY 2006 awards will be June 1, 2006.

Grants will be awarded up to $200,000 or up to $350,000 in total (direct plus indirect) costs per year for up to 3 years. Please note that beginning in FY 2006, the dollar limitation will be total costs, not direct costs as in previous years. Applications for the smaller grants ($200,000) may be for phase 1, 2, or 3 studies. Study proposals for the larger grants ($350,000) must be for studies continuing in phase 2 or 3 of investigation. Phase 1 studies include the initial introduction of an