

and elevated blood pressure are two problems that disproportionately affect minority groups. Establishing a link between blood pressure and lead exposure, especially utilizing two new biomarkers of lead exposure, bone lead and serum lead, can provide a new tool

for dealing with elevated blood pressure nationwide.

This request is for a 3-year extension. Two previously approved questionnaires will continue to be used to collect socioeconomic data, and data pertaining to risk factors for elevated blood pressure and lead exposure. A

new questionnaire assessing social stress (Scale of Chronic Social Role Stressors) and a 16 item, four response choice scale will be added to better control for social stress factors affecting blood pressure. There is no cost to respondents.

Type of respondent	No. of respondents per year	No. of responses/respondent	Avg. burden per response (in hrs)	Total burden (in hrs)
Screening Questionnaire	880	1	.5	440
Social Role Stressors	880	1	.08	70
Risk Questionnaire	330	2	.75	495
Total				1005

Dated: January 13, 1998.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Community-Based Family Resource and Support Grants.

OMB No.: 0970-0155.

Description: Application information is required when a State wishes to receive a Community-Based Family Resource and Support (CBFRS) grant

award. This Program Instruction contains information collection requirements found in Pub. L. 104-235 at Sections 202(1)(A); 202(b)(1)(B); 205; and 207. The information being collected is required by statute to be submitted pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute, complete the calculation of the grant award entitlement, provide training and technical assistance to the grantee, and evaluate State efforts in the prevention of child abuse and neglect.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application	57	1	40	2,280
Annual Report	57	1	40	1,368

Estimated Total Annual Burden Hours: 3,648.

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, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. 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 13, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98-1183 Filed 1-16-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Emergency TANF Data Report (ACF-198).

OMB No.: 0970-0164.

Description: This information is being collected to meet the statutory requirements of section 411 of the Social Security Act and section 116 of

the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. It consists of disaggregated and aggregated demographic and program information that will be used to determine participation rates and other statutorily required indicators for the

Temporary Assistance for Needy Families (TANF) program. OMB previously approved this data collection under emergency procedures through January 31, 1998. We are now requesting an extension through September 30, 1998, in order to

maintain the continuity of data collection pending OMB approval of the data collection instruments published in the NPRM dated November 20, 1997.

Respondents: States and Territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Emergency TANF Data Report	54	4	451	97,416

Estimated Total Annual Burden Hours: 97,416.

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

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, N.W., Washington, D.C. 20503, Attn: Ms. Laura Oliven.

Dated: January 7, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98-1251 Filed 1-16-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0497]

Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting submission of comments proposing product standards intended to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells derived from peripheral and cord blood for unrelated allogeneic use.¹ The comments should include supporting clinical and nonclinical laboratory data and other relevant information. This information will aid FDA in developing product standards for hematopoietic stem/progenitor cell products intended for allogeneic use in recipients unrelated to the donor (hereinafter referred to as unrelated allogeneic), including manufacturing controls and product specifications. FDA is also announcing its intention to phase-in implementation of investigational new drug application (IND) and license application requirements for minimally manipulated² unrelated allogeneic hematopoietic stem/progenitor cell products 3 years after the date of issuance of this notice to permit the development of licensing standards for those products where possible. This action is taken in response to the agency's "Proposed Approach to Regulation of Cellular and Tissue-based Products," which fulfills the objectives of the administration's "Reinventing the Regulation of Human Tissue" initiated to streamline regulatory requirements to ease the burden on regulated industry, while providing adequate protection to the public health.

¹ The term *unrelated allogeneic use* means the implantation, infusion, or transfer of a human cellular or tissue-based product from one person to another who is not a parent, sibling, or a child of the donor.

² The term *minimally manipulated* means processing of cells and nonstructural tissues that does not alter the biological characteristics and thus, potentially, the function or integrity of the cells or tissues.

DATES: Submit requested standards and supporting clinical and nonclinical laboratory data by January 20, 2000.

ADDRESSES: Submit proposed product standards and supporting data to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

A. Use of Peripheral and Cord Blood Stem/Progenitor Cells for Hematopoietic Reconstitution

The field of hematologic transplantation has changed substantially during the last two decades. Improved understanding of the diverse aspects of human hematologic precursors has facilitated their experimental manipulation. Our knowledge of their localization in humans during both fetal and postnatal development, growth regulation, differentiation, homing, and of phenotypic and functional characteristics has facilitated the development of new methods of transplantation. Traditional bone marrow transplantation, involving the extraction of bone marrow by aspiration from bone cavities with further processing by density centrifugation, is increasingly being supplanted by novel approaches that include use of hematopoietic stem/progenitor cells and biotechnologic procedures to purify and expand hematopoietic stem/progenitor cells. Human cord blood, which is enriched with pluripotent hematopoietic stem/progenitor cells, and peripheral blood, which can be enriched in hematopoietic stem/progenitor cells by a variety of