Dated: December 22, 2003.

**Ron Ergle,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 03–32166 Filed 12–30–03; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

**[ACYF/HS–2003–01]**

### Request for Public Comments on the Proposed Merger of Two Head Start Grantees in Rhode Island

**AGENCY:** Administration on Children, Youth, and Families, ACF, DHHS.

**ACTION:** Request for public comments.

**SUMMARY:** This notice is to solicit public comments and statements of interest from interested parties on the merger of two Rhode Island Head Start Programs.

**EFFECTIVE DATE:** January 30, 2004.

**FOR FURTHER INFORMATION CONTACT:** Michelle Hastings; Pal-Tech, Inc.; 1000 Wilson Blvd., Suite 1000; Arlington, VA 22209; 1–800–458–7699; 703–243–0496 (fax)

**SUPPLEMENTARY INFORMATION:** Self Help, Inc., and New Visions for Newport County, Inc. are proposing to merge their federally funded Head Start programs. This proposed merger is expected to bring about a more cost effective and efficient service delivery to children and their families. The Head Start Bureau of the Administration for Children and Families (ACF), within the United States Department of Health And Human Services has this proposal under consideration and is currently evaluating its effect on Head Start Services for children and families in the community. Under the proposed merger, Self Help, Inc., would be absorbed by New Visions for Newport County, Inc., and New Visions for Newport County, Inc. would provide Head Start services for the community it now serves as well as the community new served by Self Help, Ins.

Mergers of local Head Start grantees usually require the ACF to offer an open competition in the specified service area whose grantee is being absorbed. While this request for a merger, without a competitive review process, is under consideration, public comments are being solicited. Additionally, this notice also serves to encourage and welcome statements of interest from any local public agency, local public school system, local non-profit agency or local for-profit organization, or local faith-based organization that would want to compete for funding to provide Head Start services in the area now served by Self Help, Inc.

Self Help, Inc., also receives funding to conduct an Early Head Start program. As part of a proposed merger, Self Help, Inc., is proposing that the Early Head Start grant it conducts be transferred to New Visions for Newport County, Inc. after the merger. When an Early Head Start grantee merges with another organization, the grant must usually be recompeted, but consideration is being given to transferring the Early Head Start grant to New Visions for Newport County, Inc. While this request for a transfer, without a recompetition, is under consideration, public comments are being solicited. Additionally, this notice also serves to encourage and welcome statements of interest from any public agency, public school system, non-profit agency, for-profit organization, or faith-based organization that would want to compete for funding to provide Early Head Start services in the area now served by Self Help, Inc.

Please mail or fax statements of support or objection to this proposed merger and grant transfer as well as any request for consideration by January 30, 2004 to: Michelle Hastings; Pal-Tech, Inc.; 1000 Wilson Blvd., Suite 1000; Arlington, VA 22209; 1–800–458–7699; 703–243–0496 (fax).

Dated: December 22, 2003.

**Joan E. Ohl,**

*Commissioner, Administration on Children, Youth and Families.*

[FR Doc. 03–32151 Filed 12–30–03; 8:45 am]

**BILLING CODE 4184–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Statement of Organization, Functions, and Delegations of Authority

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (DHHS), Administration for Children and Families (ACF) as follows: Chapter KB, the Children's Bureau, Administration on Children, Youth and Families (ACYF) (66 FR 30215–18), as last amended June 5, 2001. This notice moves the Data Team from the Division of Data, Research and Innovation, Children's Bureau to the Office of the Associate Commissioner, Children's Bureau and renames the Division.

This Chapter is amended as follows:

1. Chapter KB, Administration on Children, Youth and Families.

A. Delete KB.10 Organization in its entirety and replace with the following:

*KB.10 Organization.* The Administration on Children, Youth and Families is headed by a Commissioner, who reports directly to the Assistant Secretary for Children and Families and consists of:

- Office of the Commissioner (KBA)
- Office of Management Services (KBA1)
- Head Start Bureau (KBC)
- Program Operations Division (KBC1)
- Program Support Division (KBC2)
- Program Management Division (KBC3)
- Children's Bureau (KBD)
- Office of Child Abuse and Neglect (KBD1)
- Division of Policy (KBD2)
- Division of Program Implementation (KBD3)
- Division of Research and Innovation (KBD4)
- Division of Child Welfare Capacity Building (KBD5)
- Division of State Systems (KBD6)
- Family and Youth Services Bureau (KBE)
- Child Care Bureau (KBG)
- Immediate Office/Administration (KBG1)
- Program Operations Division (KBG2)
- Policy Division (KBG3)
- Technical Assistance Division (KBG4)

B. Delete KB.20 Functions, Paragraph D introductory material, in its entirety and replace with the following:

D. The Children's Bureau is headed by an Associate Commissioner who advises the Commissioner, Administration on Children, Youth and Families, on matters related to child welfare, including child abuse and neglect, child protective services, family preservation and support, adoption, foster care and independent living. It recommends legislative and budgetary proposals, operational planning system objectives and initiatives, and projects and issue areas for evaluation, research and demonstration activities. It represents ACYF in initiating and implementing interagency activities and projects affecting children and families, and provides leadership and coordination for the programs, activities, and subordinate components of the Bureau. It is responsible for the Data and Technology Team which

analyzes and disseminates program data from the Adoption and Foster Care Analysis and Reporting System (AFCARS), and the National Child Abuse and Neglect Data System (NCANDS); develops systematic methods of measuring the impact and effectiveness of various child welfare programs; performs statistical sampling functions; provides comprehensive guidance to States, local agencies and others on data collection issues, and performance outcome measures; and is the focal point for technology development within the Bureau.

C. Delete KB.20 Functions, Paragraph D.4, in its entirety and replace with the following:

4. The Division of Research and Innovation provides leadership and direction in program development, innovation, research and in the management of the Bureau's information systems under titles IV–B and IV–E of the Social Security Act, and under the Child Abuse Prevention and Treatment Act. It defines critical issues for investigation and makes recommendations regarding subject areas for research, demonstration and evaluation. It administers the Bureau's discretionary grant programs, and awards project grants to State and local agencies and organizations nationwide. It provides direction to the Crisis Nurseries and Abandoned Infants Resource Centers.

Dated: December 9, 2003.

**Wade F. Horn,**

*Assistant Secretary for Children and Families.*

[FR Doc. 03–31374 Filed 12–30–03; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2003N–0268]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biological Products: Reporting of Biological Product Deviations in Manufacturing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by January 30, 2004.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Biological Products: Reporting of Biological Product Deviations in Manufacturing—(OMB Control Number 0910–0458)—Extension

Under section 351 of the Public Health Service Act (42 U.S.C. 262), all biological products, including human blood and blood components, offered for sale in interstate commerce must be licensed and meet standards designed to ensure the continued safety, purity, and potency of such products. In addition, section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351) provides that drugs and devices (including human blood and blood components) are adulterated if they do not conform with current good manufacturing practice (CGMP) assuring that they meet the requirements of the act. All establishments manufacturing human blood and blood components are required to register with FDA, and comply with the CGMP regulations for human blood and blood components (parts 211 and 606 (21 CFR parts 211 and 606)). Transfusion services are required under 42 CFR 493.1273(a) to comply with part 606 and 21 CFR part 640 as they pertain to the performance of manufacturing activities. FDA regards biological product deviation reporting to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information. Section 600.14 (21 CFR 600.14) requires the licensed manufacturer who holds the biological product license, for other than human blood and blood components, and who had control over the product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Section 606.171 requires a licensed manufacturer of human blood and blood components, including Source Plasma; an unlicensed registered blood establishment; or a transfusion service who had control over the product when the deviation occurred, to report to CBER as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Respondents to this collection of information are the licensed manufacturers of biological products other than human blood and blood components, unlicensed registered blood establishments, and transfusion services. Based on information from CBER's databases for fiscal year (FY) 2002, there were 115 licensed manufacturers of biological products other than human blood and blood components, 207 licensed manufacturers of human blood and blood components, including Source Plasma, and 2,800 unlicensed registered blood establishments and 3,221 transfusion services. However, not all manufacturers or establishments may have any submissions in a given year and some may have multiple submissions. In the same FY, CBER's database also showed that the licensed manufacturers of biological products other than human blood and blood components submitted 476 biological product deviation reports (BPDRs) under § 600.14, the licensed manufacturers of human blood and blood components, including Source Plasma submitted 27,000 BPDRs under § 606.171, and the unlicensed registered blood establishments and transfusion services submitted a total of 6,446 BPDRs. The number of total annual responses is based on the number of BPDRs CBER received in FY 2002. The rate of submission is not expected to change significantly in the next few years. Based on information from industry, the estimated average time to complete a deviation report is 2 hours. The availability of the standardized report FDA Form 3486, and the ability to submit this report electronically further streamlines the report submission process. Activities such as investigating, changing standard operating procedures (SOPs) or processes, and followup are currently required under parts 211 (approved under OMB control numbers 0910–0139