

County, and Wayne County. These counties are unserved and open for competition for Early Head Start Programs.

On page 10803 the State column mistakenly lists Nuckolls. Nuckolls is a county in Nebraska and should appear in the county column. The county is currently being served and is not open for competition to new Early Head Start programs.

On page 10804, in New York State, Westchester County, in the community column it should read "excluding White Plains, New York." The County is being served, except for White Plains. Only White Plains is open to competition for new Early Head Start programs.

On page 10806, for Rhode Island, Bristol County, the community of Barrington should be added to the communities of Bristol and Warren. In Rhode Island, Providence County, the City of Cranston and the towns of E. Providence and Central Falls should be added to the towns of: Burrillville, Johnston, N. Providence, Smithfield, N. Smithfield, Glocester, Scituate and Foster. All these communities are currently being served and are not open for competition to new Early Head Start programs.

On page 10808, in Texas, in the County column, Tarran is misspelled and should be corrected to read Tarrant County. This county is currently being served and is not open to competition to new Early Head Start programs.

FOR FURTHER INFORMATION CONTACT: The ACYF Operations Center at 1-800-351-2293 or send an email to ehs@lcnnet.com. You can also contact Judith Jerald, Early Head Start, Head Start Bureau at (202) 205-8074.

Dated: April 3, 2000.

Patricia Montoya,

Commissioner, Administration on Children, Youth and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Developmental Disabilities 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 KC, Administration on Developmental Disabilities (ADD), 56 FR 42338, dated August 27, 1991. This Notice reflects a revised ADD mission statement to reflect current legislative references and a realignment of functions within the Office of ADD.

I. Delete KC.00 Mission in its entirety and replace with the following:

KC.00 Mission. The Administration on Developmental Disabilities (ADD) advised the Secretary, through the Assistant Secretary for Children and Families, on matters relating to individuals with developmental disabilities and their families. ADD serves as the focal point in the Department to support and encourage the provision of quality services to individuals with developmental disabilities and their families. ADD assists states, through the design and implementation of a comprehensive and continuing state plan, in increasing the independence, productivity and community inclusion of individuals with developmental disabilities. These state plans make optimal use of existing federal and state resources for the provision of services and supports to these individuals and their families to achieve these outcomes. ADD works with states to ensure that the rights of all individuals with developmental disabilities are protected.

ADD administers two formula grant programs, State Developmental Disabilities Councils and Protection and Advocacy Systems, and two discretionary grant programs, University Affiliated Programs and Projects of National Significance, including Family Support. These programs support the provision of services to individuals with developmental disabilities and their families. In concert with other components of ACF as well as other public, private, and voluntary sector partners, ADD develops and implements research, demonstration and evaluation strategies for discretionary funding of activities designed to improve and enrich the lives of individuals with developmental disabilities. In addition, ADD serves as a resource in the development of policies and programs to reduce or eliminate barriers experienced by individuals with developmental disabilities through the identification of promising practices and dissemination of information. ADD supports and encourages programs or services, which prevent developmental disabilities and manages initiatives involving the private and voluntary sectors that benefit individuals with developmental and other disabilities and their families.

II. Delete KC.10 Organization in its entirety and replace with the following:

KC.10 Organization. The Administration on Developmental Disabilities is headed by a Commissioner who reports directly to the Assistant Secretary for Children and Families. The Administration on Developmental Disabilities consists of: Office of the Commissioner (KCA) Program Operations Division (KCB) Program Development Division (KCC)

III. Delete KC.20 Functions in its entirety and replace with the following:

KC.20 Functions. A. The Office of the Commissioner (OC) serves as the principal advisor to the Assistant Secretary for Children and Families, the Secretary, and other elements of the Department for individuals with developmental disabilities. OC provides executive direction and management strategy to ADD's components and establishes goals and objectives for ADD programs. The Deputy Commissioner assists the Commissioner in carrying out the responsibilities of the Office and acts as Commissioner in the absence of the Commissioner. The Staff within the office of the Commissioner plans, coordinates and controls ADD policy, planning, and management activities which include the development of legislative proposals, regulations and policy issuances for ADD. The Staff manages the formulation and execution of the program and operating budgets; provides administrative, personnel and information systems support services; serves as the ADD Executive Secretariat controlling the flow of correspondence; and coordinates with appropriate ACF components in implementing administrative requirements and procedures. The staff also coordinates interagency collaboration, program outreach, and convenor functions.

In coordination with the ACF Office of Public Affairs, OC develops a strategy for increasing public awareness of the needs of individuals with developmental disabilities and programs designed to address them.

B. Division of Program Operations (POD) is responsible for the coordination, management, and evaluation of the State Developmental Disabilities Councils Program and the Protection and Advocacy Grants Program, including the development of procedures and performance standards that ensure compliance with the Developmental Disabilities Assistance and Bill of Rights (DD) Act and improve the outcomes of Developmental Disabilities Councils and Protection and Advocacy Systems in increasing the independence, productivity and

community inclusion of persons with developmental disabilities.

The Division conducts routine and special analyses of state plans under the Basic State Grants Program, including an examination of priority area activities, to assure consistent application of ADD program goals and objectives. The Division conducts reviews of programs to ensure compliance with the DD Act and to improve program outcomes; and identifies and disseminates information regarding excellence in advancing the independence, productivity and community inclusion of people with developmental disabilities.

The Division initiates, executes, and supports the development of interagency, intergovernmental, and public-private sector agreements, committees, task forces, commissions, or joint funding efforts as appropriate.

The Division provides program and administrative guidance to regional offices on matters related to the implementation of the DD Act; and ensures timely and effective communication with the regional offices regarding program compliance, policy clarification, and the approval of required state plans and reports.

C. Division of Program Development (PDD) manages the discretionary grants and contracts mandated by the DD Act, and provides program development services. PDD originates cross-cutting research, demonstration and evaluation initiatives with other components of ADD, ACF, HHS, and other government agencies; and manages discretionary grants and contracts and assists in monitoring and evaluating discretionary grants at the national level.

The Division plans for and implements experimental program services based on advice from state and local organizations on program needs. The Division formulates and prepares annual demonstration and evaluation plans, coordinates and administers the University Affiliated Programs (UAP's) activities, and develops quality assurance criteria for the UAP Program.

The Division develops and initiates guidelines, policy issuances and actions with team participation by other components of ADD, ACF, HHS, and other government agencies to fulfill the mission and goals of the DD Act, as amended. The Division ensures the dissemination of project results and information produced by ADD grantees.

The Division coordinates national program trends with other ACF programs and HHS agencies; and studies, reviews and analyzes other federal programs providing services applicable to persons with

developmental disabilities for the purpose of integrating and coordinating program efforts.

Dated: March 30, 2000.

Sue Swenson,

Commissioner, Administration on Developmental Disabilities.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0529]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry: Changes to an Approved NDA or ANDA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by May 8, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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.

Guidance for Industry: Changes to an Approved NDA or ANDA

On November 21, 1997, the President signed into law the FDA Modernization Act (the Modernization Act) (Public Law 105-115). Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which describes requirements and procedures for making and

reporting manufacturing changes to approved new drug applications (NDA's) and abbreviated new drug applications (ANDA's), to new and abbreviated animal drug applications, and to license applications for biological products.

The guidance provides recommendations to holders of approved NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act. The guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes.

Section 116 of the Modernization Act amended the act by adding section 506A, which includes the following provisions:

1. A drug made with a manufacturing change, whether a major manufacturing change or otherwise, may be distributed only after the applicant validates the effects of the change on the identity strength, quality, purity, and potency of the drug as these factors may relate to the safety or effectiveness of the drug (section 506A(a)(1) and (b) of the act). This section recognizes that additional testing, beyond testing to ensure that an approved specification is met, is required to ensure unchanged identity, strength, quality, purity, or potency as these factors may relate to the safety or effectiveness of the drug.

2. A drug made with a major manufacturing change may be distributed only after the applicant submits a supplement application to FDA and the supplemental application is approved by the agency. The application is required to contain information determined to be appropriate by FDA and include the information developed by the applicant when "validating the effects of the change" (section 506A(c)(1) of the act).

3. A major manufacturing change is a manufacturing change determined by FDA to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug. Such changes include: (1) A change made in the qualitative or quantitative formulation of the drug involved or in the specifications in the approved application or license unless exempted by FDA by regulation or guidance; (2) a change determined by FDA by regulation or guidance to require