be obtained from Ms. Linda LaChanse, Program Analyst, Training and Technical Support Systems Branch, Division of HIV/AIDS Prevention, National Center for HIV/STD/TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop E–40, Atlanta, GA 30333, telephone (404) 639–0964.

Please refer to Announcement Number 802 when requesting information, submitting your Letter of Intent and submitting the invited application in response to the announcement.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800. Single copies of CDC's Strategic Plan for Preventing Human Immunodeficiency Virus (HIV) Infection (July 8, 1992) can be obtained by calling the CDC National AIDS Clearinghouse at (800) 458–5231.

Dated: December 11, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–32867 Filed 12–16–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Head Start Program; Notice of Award

AGENCY: Administration on Children, Youth and Families, Administration for Children and Families, HHS.

ACTION: Notice of Sole Source Award to Administer the Head Start Child Development Credentialing Program.

SUMMARY: The Head Start Bureau announces its intention to enter into a noncompetitively awarded cooperative agreement with The Council for Early Childhood Professional Recognition to administer the Child Development Associate (CDA) Credentialing Program. The CDA Program is a national project to credential qualified caregivers who work with children birth to age five in a variety of public and private agency settings, and in a variety of roles, including as center-based caregivers of infants and toddlers or preschool age children, as home visitors, or as family child care providers.

If there are organizations interested in competing for this grant to administer the Head Start Child Development Credentialing Program, they are requested to express their interest by contacting either E. Dollie Wolverton or Lynda Perez by January 16, 1998.

DATES: Effective on January 16, 1998.

FOR FURTHER INFORMATION CONTACT: E. Dollie Wolverton, Head Start Bureau, ACYF, P.O. Box 1182, Washington, D.C. 20013, (202) 205–8418 (Not a toll free call); or Lynda Perez, Grants Officer, Head Start Bureau, ACYF, P.O. Box 1182, Washington, D.C. 20013, (202) 205–7359 (Not a toll free call).

SUPPLEMENTARY INFORMATION:

I. Background

The project period for this cooperative agreement will be four years. The award is approximately $1,000,000 annually. The authority for this credentialing program is section 648(e) of the Head Start Act (42 U.S.C. 9843).

The Head Start Program is committed to staff development for all individuals employed in local programs to increase the understanding and skills necessary to carry out their jobs, as well as professional development leading to credentials and degrees. In addition to ongoing staff development, section 648A of the Head Start Act directs the Secretary to ensure that each of the 55,000 Head Start classrooms for preschool-age children has a qualified teacher, with a minimum of a CDA credential.

Those who are credentialed include prekindergarten staff from the various military sectors, child care, church-affiliated preschools, Title I school-based programs, and Head Start. Also, the revised Head Start Program Performance Standards, which become effective January 1, 1998, include new standards for infant and toddler programs and the requirement that infant and toddler teachers also be qualified by January 1, 1999, and thereafter within one year of hire, holding a CDA credential at a minimum.

Beginning in 1972, ACYF has supported various organizations to administer the CDA National Credentialing Program. These organizations included a Consortium of several child development and early childhood education associations and the Bank Street College of Education. The first decade of this credential award program was unstable and problematic due, in large measure, to the fact that the grant was recompeted frequently, leading to several changes in administering organizations and resulting breaks in services. The general instability and under-use of the CDA credential system caused concern to the Department and the Congress. The Department requested that the National Association for the Education of Young Children create a non-profit subsidiary to become a free standing organization that would permanently administer the CDA credentialing program. Accordingly, the Council for Early Childhood Professional Recognition was established to administer the national CDA Credentialing Program through a cooperative agreement. The intent of maintaining a permanent home for the national Child Development Associate credentialing program was reinforced in 1992, when Section 7 of the 1992 Juvenile Justice Act, entitled, ''Head Start Training Improvement,'' amended the Head Start Act, requiring the funding of an organization to administer a centralized child development credential and national assessment program.

II. Reason for Sole Source Award

The Council for Early Childhood Professional Recognition has effectively restored public confidence in the CDA Credential and increased the number of credentials awarded. The number of candidates credentialed each year has steadily grown from about 2,000 credentialed candidates annually to nearly 8,000 per year. As of June 1997, nearly 83,000 teachers, home visitors and family child care providers have been credentialed. The Council has also increased the recognition and credibility of the CDA Credential among the States, and now 47 States, the District of Columbia and Puerto Rico recognize the Child Development Associate credential as the requirement for the licensing of a child care center. This provides those certified with the CDA credential with the mobility to move from State-to-State with State recognition of their credential and qualifications.

The Council is efficiently and cost-effectively administering the National CDA Credentialing Program at a time when the demand for the credential has greatly increased. This allows the Council to maintain the assessment and credentialing fee to the candidate (the majority are low-income) at $325.

Because of the mandate for qualified teachers of infants and toddlers and preschool age children, welfare reform, and the President's intended expansion of the Head Start Program to serve one million eligible children by the year 2002, the need for qualified, credentialed staff is an urgent matter, particularly given the annual turnover rate of 17 percent among Head Start staff. To address the expansion of the

Head Start Program and the expansion of services by other agencies providing child care and early childhood education, it is estimated that approximately 8,000 CDA candidates will require assessment and a credential award during each of the next four years.

In the face of these challenges, the Department seeks to ensure the continuity of the administration of this unique national credentialing program, which provides affordable credentialing award services which are nationally recognized, cost effective, represent quality standards for staff working with children ages birth to five years, and enjoy the confidence of the States, institutions of higher learning, and the field of early childhood.

(Catalog of Federal Domestic Assistance Program Number 93.600, Project Head Start)

Dated: December 11, 1997.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 97–32954 Filed 12–16–97; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0430]

Medical Devices; Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA.'' The guidance document provides suggestions for the nonclinical laboratory studies and the design, conduct, and analysis of appropriate clinical studies that the Center for Devices and Radiological Health (CDRH), FDA, believes will provide reasonable assurance of the safety and effectiveness of these devices. The guidance document also sets forth the review criteria and describes the data to support a 510(k) submission. The guidance accompanies a final rule, which appears elsewhere in this issue of the **Federal Register**, announcing the reclassification of tumor associated antigen immunological test systems from class III (premarket approval) to class II (special controls).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written comments concerning this guidance document to the contact person listed below. Submit written requests for single copies of ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA'' to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist the office in processing your request, or fax your request to 301–443–8818. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued an order (September 19, 1996) in the form of a letter reclassifying tumor associated antigen immunological test systems from class III to class II. The order identified the premarket notification guidance document for tumor associated antigens as one of the designated special controls. The guidance document contains general information on the definition of qualifying devices and the administrative requirements for submitting a 510(k) to FDA. The document also lists the types of nonclinical (analytical) studies to be included in the submission. These studies include reagent characterization, assay specificity, and device performance characteristics to include precision, linearity, interfering substances, analytical sensitivity and methods of comparison to another device. Finally, the document provides guidance on the design of clinical studies to support a submission for a new tumor marker intended to monitor previously treated patients.

This guidance document represents the agency's current thinking on the design of clinical studies expected to support a 510(k) submission for new tumor markers intended to monitor previously treated patients. 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 statute, regulation, or both.

II. Requests for Comments

Interested persons may, at any time, submit to the contact person listed above written comments regarding this guidance document. Two copies of any 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.

III. Electronic Access

In order to receive the ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 1–800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (957) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). The CDRH maintains an entry on the WWW for easy access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA'' will be available at http://www.fda.gov/cdrh/ode/ed—cl.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 1–800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES