Manufacturing, and Control (CMC) Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications (INDs)'' dated August 2003. The draft guidance document, when finalized, will provide instructions to CMC reviewers of human somatic cell therapies on what information should be recorded and assessed as part of their review of an original IND. The draft guidance document, when finalized, will also provide CMC reviewers the format in the corresponding human somatic cellular therapy CMC template to prepare their reviews.

DATES: Submit written or electronic comments on the draft guidance by November 17, 2003, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, 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

FDA is announcing the availability of a draft document entitled ''Guidance for Reviewers: Instructions and Template for Chemistry, Manufacturing, and Control (CMC) Reviewers of Human Somatic Cell Therapy Investigational New Drug Applications (INDs)'' dated August 2003. The draft guidance document provides instructions and a template that are intended to be tools to assist CMC reviewers of human somatic cell therapy INDs. The draft guidance document is intended to help ensure that all applicable regulatory requirements are reviewed for the appropriate stage of product development.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will provide instructions to CMC reviewers of human somatic cell therapies on what information should be recorded and assessed as part of their review of an original IND. 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 requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: August 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–20950 Filed 8–15–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[Announcement Number: HRSA–03–110]

Maternal and Child Health Federal Set-Aside Program; Special Projects of Regional and National Significance; State Oral Health Collaborative Systems (SOHCS) Grant Program (CFDA #93.110)

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that approximately $2,950,000 in fiscal year (FY) 2003 funds is available to fund up to 59 one-year grants to support States' efforts to develop, implement or otherwise strengthen State oral health collaborative strategies that increase access to oral health services for Medicaid and State Children's Health Insurance Program (SCHIP) eligible children, and other underserved children and their families. Eligibility is open to MCH agencies in the 50 States and nine specified jurisdictions, unless another governmental or non-governmental agency is approved. Awards will be made under the program authority of section 501(a)(2) of the Social Security Act, the Maternal and Child Health (MCH) Federal Set-Aside Program (42 U.S.C. 701(a)(2)), *i.e.,* Special Projects of Regional and National Significance (SPRANS). Funds for these awards were appropriated under Pub. L. 108–07, the ''Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2003.'' Up to $50,000 in FY 2003 funds is available for each one-year grant; up to an additional $50,000 in FY 2003 funds may become available for the grant during the course of the same one-year project period, depending upon the availability of funds.

DATES: The deadline for receipt of applications is August 25, 2003. *Applicants are required to submit one ink-signed original and two copies of the completed application.* The projected award date will be prior to September 30, 2003.

ADDRESSES: To receive a complete application kit, applicants may telephone the HRSA Grants Application Center at 1–877–477–2123 (1–877–HRSA–123) beginning July 25, 2003, or register on-line at: *http://www.hrsa.*

gov/, or by accessing *http://www.hrsa.gov/g_order3.htm* directly. This program uses the standard Form PHS 5161–1 (rev. 7/00) for applications (approved under OMB No. 0920–0428). Applicants must use the appropriate Catalog of Federal Domestic Assistance (CFDA) number 93.110 and the title, ''State Oral Health Collaborative Systems Program,'' when requesting application materials. The CFDA is a Government-wide compendium of enumerated Federal programs, projects, services, and activities that provide assistance. Unless submitted on-line (*see* next paragraph), all applications should be mailed or delivered to: Grants Management Officer (MCHB), HRSA Grants Application Center (GAC), 901 Russell Avenue, Suite 450, Gaithersburg MD, telephone: 1–877–HRSA–123 (477–2123), e-mail: *hrsagac@hrsa.gov*. Notice of receipt of applications will be sent by the GAC.

Applicants should note that HRSA anticipates accepting grant applications online in the last quarter of the Fiscal Year (July through September). Please refer to the HRSA grants schedule at *http://www.hrsa.gov/grants.htm* for more information. The automated application process should be faster, easier and better for applicants and for HRSA. We encourage you to take advantage of this new option. Applicants will be notified through the same channels that currently announce the availability of downloadable and paper application materials, including notices on HRSA Web sites and e-mail communications. Once the automated system is in place, applications can be submitted on-line and applicants will receive an electronic confirmation of the submission. Applicants will need to print the face page, sign it, and submit it to the HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879; telephone 1–877–477–2123.

FOR FURTHER INFORMATION CONTACT: Mark E. Nehring, DMD, MPH, 301–443–1080, e-mail: *mnehring@hrsa.gov* (for questions specific to project activities of the program, program objectives, or the Letter of Intent described above); and Mona D. Thompson, 301–443–3429; e-mail, *mthompson@hrsa.gov* (for grants policy, budgetary, and business questions).

SUPPLEMENTARY INFORMATION:

Program Background and Objectives: Today, MCHB is the principal Federal agency supporting State dental programs. Most State dental programs are organizationally part of the State's maternal and child health (MCH) program. Nearly 80 percent of State dental program funds come from Federal MCH Block Grants to States funds. MCHB provides the infrastructure for most oral health prevention and services programs in our Nation. MCHB-sponsored programs have considerable flexibility and legislative authority to support State dental programs and to develop partnerships between the public and private sectors to address the needs of all mothers and children. This critical role, however, is not matched with sufficient resources to meet demand.

Despite tremendous advances in prevention, dental caries remains the predominant childhood disease, continuing to take a heavy toll on children's health and well-being across all socioeconomic, racial, and ethnic groups. Increasingly, we are witnessing a concentration of dental illness both in quantity and severity among children living in poverty and of racial and ethnic minorities. From all available data it is clear that in most parts of our nation, inadequate access to dental care is commonplace for children of families living in poverty.

In order for children to be raised in healthy families and communities, all community service systems, including oral health, need to take ownership of the problems and solutions associated with assuring children's access to comprehensive systems of quality care. Nationwide, there is a growing body of evidence documenting the serious obstacles impeding oral health care access, not the least of which is an inadequate number, distribution and availability of providers for the nation's most needy children. Current systems of health, education, social services and child care are often crisis oriented and designed to address problems that have already occurred rather than proactively oriented to prevent them. These systems tend to divide the problems of children, families, and communities into rigid categorical programs that fail to reflect interrelated causes and solutions. This categorical organization of service systems makes it impossible for the current systems to meet the needs of children, families, and communities. Truly effective and sustainable successes can be achieved through building integrated partnerships that make a firm commitment to implementing programs and policies that are creative, comprehensive and collaborative.

Authorization: Section 501(a)(2) of the Social Security Act (42 U.S.C. 701(a)(2)).

Purpose: This purpose of this grant program is to support States' efforts to develop, implement or otherwise strengthen State oral health collaborative strategies that increase access to oral health services for Medicaid and State Children's Health Insurance Program (SCHIP) eligible children, and other underserved children and their families. These grants are intended to address the cross-cutting oral health needs of women and children. These needs range from broad-based interventions such as strategic planning, public/private partnerships and comprehensive integrated support systems to more narrowly focused interventions such as early childhood decay, sealant and prevention programs. These efforts follow up:

1. Findings contained in the Office of the Inspector General Report: Children's Dental Service Under Medicaid Access and Utilization, and Oral Health in America: A Report of the Surgeon General.

2. The Health Resources and Services Administration (HRSA)/Centers for Medicaid and Medicare Services (CMS) sponsored conference, Building Partnerships to Improve Access to Medicaid Oral Health Services.

3. The American Dental Association (ADA) sponsored Achieving Improvement in Medicaid—AIM for Change meeting held in Chicago, Illinois, August 2–3, 1999.

4. Recommendations for State strategic plans developed through State Oral Health Summit meetings, National Governors Association (NGA) Policy Academies and/or Head Start Forums.

5. Maternal and Child Health Bureau (MCHB) performance measures addressing the presence of sealants on third grade student molars, enrollment in Medicaid/SCHIP and/or the presence of essential elements in State Oral Health Plans.

6. The report Oral Health in America: A Report of the Surgeon General, and subsequent release of A National Call to Action to Promote Oral Health.

Eligibility: States (defined in this offering as States and Jurisdictions) are eligible to apply for State Oral Health Collaborative Systems Grant funding, unless the State specifically requests and designates another State-approved government or non-government agency and provides a convincing justification for so doing. States designating another agency must submit an endorsement acknowledging that the applicant has consulted with the State and that the State has been assured that the applicant will work with the State on the proposed project. This endorsement must accompany the application. Without the endorsement, the application will not be considered for funding. Because of the importance of linking oral health activities with

systems of care for children, the involvement of the State MCH program is strongly encouraged. Such involvement could be demonstrated either by a co-signed application or by a letter of support.

Funding Level/Project Period: Approximately $2,950,000 is available for the State Oral Health Collaborative Systems grants during FY 2003. These awards will be made not to exceed $50,000 (including indirect costs) per award, per year, for a project period of one year, beginning approximately September 01, 2003. The applicant is invited, within this same application, to apply for up to an additional $50,000, should funds become available or fewer than fifty-nine applications are approved and recommended for funding. To be considered for additional funding, States must submit an addendum to the application to include a revised face page (SF 424), budget and budget justification that would support an increased scope of work and requested funding level, up to $50,000, inclusive of indirect costs, and is in keeping with the programmatic objectives of this grant offering. Finally, cost sharing or matching is not required or encouraged under the SOHCS grant program.

Review Criteria: Applications that are complete and responsive to the guidance will be evaluated by an objective review panel specifically convened for this solicitation and in accordance with HRSA grants management policies and procedures.

Applications will be reviewed using the following HRSA criteria:

1. Description of the Problem—The extent to which the project describes the severity of oral health needs of the community.

2. Goals & Objectives ''Major goals and objectives are clearly stated and attainable for the project period.

3. Implementation Plan—The quality of the project plan or methodology is adequately explained indicating the extent to which the project will contribute to the advancement of maternal and child health and/or improvement of the oral health of underserved children as measured through MCHB performance measures addressing the presence of sealants on third grade student molars, enrollment in Medicaid/SCHIP and/or the presence of essential elements in State Oral Health Plans.

4. Partnerships (Collaborative Agencies and Programs)—The extent to which the project demonstrates commitment of prospective partners and strength of the applicant's plan for integrating oral health into existing public and private health systems.

5. Budget—The extent to which the estimated cost to the Government of the project is reasonable, considering the anticipated results.

Paperwork Reduction Act: OMB approval for any data collection in connection with this grant program will be sought, as required under the Paperwork Reduction Act of 1995.

Public Health System Reporting Requirements: This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937–0195). Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

(a) A copy of the face page of the application (SF 424).

(b) A summary of the project (PHSIS), not to exceed one page, which provides:

(1) A description of the population to be served.

(2) A summary of the services to be provided.

(3) A description of the coordination planned with the appropriate State and local health agencies.

Executive Order 12372: The MCH Federal Set-Aside program has been determined to be a program which is not subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

Dated: August 13, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–21197 Filed 8–14–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974: Revision to Existing System of Records

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notification of an altered system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, HRSA is publishing a notice of a proposal to revise an existing system of records, 09–15–0055, Organ Procurement and Transplantation Network (OPTN) Data System.

DATES: Effective Date: The modifications to this system will become effective without further notice on September 29, 2003, unless comments dictate otherwise. *Comment Date*: To be considered, written comments must be received on or before September 29, 2003.

ADDRESSES: Written comments should be addressed to James Burdick, M.D., Director, Division of Transplantation, Office of Special Programs, Health Resources and Services Administration, Parklawn Building, Room 16C–17, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: James Burdick, M.D., Director, Division of Transplantation, Office of Special Programs, HRSA, Parklawn Building, Room 16C–17, 5600 Fishers Lane, Rockville, Maryland 20857. The telephone number is 301–443–7577.

SUPPLEMENTARY INFORMATION: The current Notice of System of Records requires updated and expanded information in several sections, *e.g.*, Name, System Locations, Categories of Records in the System, Purpose, Safeguards, and Retention and Disposal. In addition, this notice updates and modifies the routine uses of this Notice. Data collected by the OPTN are shared on a monthly basis with the contractor for the Scientific Registry of Transplant Recipients (SRTR) and HRSA's Division of Transplantation (DoT), the Federal entity that oversees the OPTN and SRTR contracts. The notice is published below in its entirety, as amended.

The definitions of the final rule governing the operation of the OPTN (42 CFR part 121) apply to this System of Records Notice.