

7. The column for Adults is divided into two age groups. Adults are counted as either "Adults Age 59 or younger" or "Adults Age 60 or older". A column for total adults is also included, which can be used by States who do not know the age breakout of the adult recipients. This more detailed reporting of Adults will allow considerably greater detailed analyses of the use of SSBG for specific services.

8. The order of two services, special services for youth at risk and special services for the disabled, has been changed from the previous version of the post-expenditure report form so that services are in the correct alphabetical order.

The Social Services Block Grant program (SSBG) provides funds to assist States in delivering social services directed towards the need of children and adults in the State. Funds are allocated to the States in proportion to their populations. States, including the District of Columbia, Guam, Puerto Rico, Virgin Islands, Northern Mariana Islands, and American Samoa have substantial discretion in their use of

funds and may determine what services will be provided, who will be eligible, and how funds are distributed among the various services. State or local SSBG agencies (*i.e.*, county, city, regional offices) may provide the services or may purchase them from qualified agencies, organizations or individuals. States report as recipients of SSBG-funded services any individuals who receive a service funded at least partially by SSBG.

States are required to report their annual SSBG expenditures on a standard post-expenditure report, which includes a yearly total of adults and children served and annual expenditures in each of 29 service categories. Reporting requirements for SSBG were originally described in the **Federal Register**, Volume 58, Number 218, on Monday November 15, 1993. The annual report is to be submitted within six months of the end of the period covered by the report, and must address (1) the number of individuals (as well as number of children and number of adults) who receive services paid for in whole or in part with federal

funds under the Social Services Block Grant; (2) the amount of Social Services Block Grant funds spent in providing each service; (3) the total amount of federal, state and local funds spent in providing each service, including Social Services Block Grant funds; and (4) the method(s) by which each service is provided, showing separately the services provided by public agencies, private agencies.

Information collected on the post-expenditure report is analyzed and described in an annual report on SSBG expenditures and recipients produced by the Office of Community Services. The information contained in this report is used to establish how SSBG funding is used for the provision of services in each State to each of many specific populations of needy individuals.

Respondents: This report is completed once annually by a representative of the agency that administers the Social Services Block Grant at the State level in each State, the District of Columbia and the Territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Post-Expenditure Report	56	1	110	6160
Estimated Total Annual Burden Hours:	6160

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, 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 24, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01-2463 Filed 1-26-01; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Child Support Enforcement; 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 KF, the Office of Child Support Enforcement (OCSE) as last amended October 6, 1999 (64 FR 54330). This reorganization will create an Office of Deputy Commissioner and abolish the Office of Central Office Operations. It establishes three new Divisions within OCSE—the Division of Management Services, the Division of Planning, Research and Evaluation and the Division of Special Staffs. In addition, this reorganization renames two Divisions and reassigns functions and reporting responsibilities.

I. Amend Chapter KF as follows:

a. *KF.00 Mission.* Delete in its entirety and replace with the following:

KF.00 Mission. The Office of Child Support Enforcement (OCSE) advises the Secretary, through the Assistant Secretary for Children and Families/Director of Office of Child Support Enforcement, on matters relating to child support enforcement. OCSE, in conjunction with Regional Offices, provides direction, guidance and

oversight to State and tribal Child Support Enforcement (CSE) program offices and Tribes for activities authorized and directed by title IV-D of the Social Security Act and other pertinent legislation. The general purpose of the CSE legislation is to permit State and tribes to develop programs for establishing and enforcing support obligations by locating noncustodial parents, establishing paternity when necessary, obtaining child support orders, and enforcing those orders. The specific responsibilities of this Office are to: develop, recommend and issue policies, procedures and interpretations for State and tribal programs for locating non-custodial parents, establishing paternity, and obtaining child support; develop procedures for review and approval or disapproval of State and tribal plan material; conduct audits of child support programs; assist State and tribes in establishing adequate reporting procedures and maintaining records for the operation of the CSE programs and of amounts collected and disbursed under the CSE program and the costs incurred in collecting such amounts; provide technical assistance and training to the State and tribes to help them develop effective procedures and systems for establishing paternity, establishing support orders and collecting child support; operate the law enforcement, military and judicial liaison offices; operate the United State and tribes Central Authority for International Child Support; monitor the access, visitation and fatherhood programs. OCSE also operates the mandatory and discretionary grant programs for child support as well as several other components within the Administration for Children and Families; and reviews and manages the clearance of **Federal Register** Notices for OCSE, and various components of ACF. It also coordinates the child support provisions of the Welfare-to-Work program; certify applications from State and tribes for permission to utilize the courts of the United State and tribes to enforce court orders for support against absent parents; operate the Federal Parent Locator Service (FPLS); certify to the Secretary of the Treasury amounts of child support obligations that require collection in appropriate instances; transmits to the Secretary of State certifications of arrearages for passport denial; submit reports to Congress, as requested, on activities undertaken relative to the CSE program; approve advanced data processing planning documents; and review, assess and inspect planning, design and operation

of State and tribal management information systems. The FPLS also assists other Federal and State and tribal agencies not involved in child support to fulfill their respective missions, save taxpayer dollars, and improve service to the public.

b. *KF.10 Organization.* Delete in its entirety and replace with the following:

KF.10 Organization. The Office of Child Support Enforcement is headed by a Director and consists of:
Office of the Director & Deputy Director/
Commissioner (KFA)
Office of Audit (KFB1)
Office of Deputy Commissioner
Division of Consumer Services (KFA-2)
Division of Management Services (KFA3)
Division of Planning, Research, and Evaluation (KFA4)
Division of Policy (KFB5)
Division of State, Tribal and Local Assistant (KFB6)
Division of Special Staffs (KFA6)
Office of Automation and Program Operations (KFC)
Division of Federal Systems (KFC5)
Division of State and Tribal Systems (KFC4)
Office Grants Management (KFD)
Office of Mandatory Grants (KFG)

KF.20 Functions.

KFA. Office of the Director and Deputy Director/Commissioner. The Director is also the Assistant Secretary for Children and Families and is directly responsible to the Secretary for carrying out OCSE's mission. The Deputy Director/Commissioner has day-to-day operational responsibility for Child Support Enforcement programs. The Deputy Director/Commissioner assists the Director in carrying out responsibilities of the Office and provides direction and leadership to the Office of the Deputy Commissioner, the Office of the Automation and Program Operations, Office of Audit, Office of Grants Management, and Office of Mandatory Grants.

The Office is responsible for developing regulations, guidance and standards for State/Tribes to observe in locating absent parents; establishing paternity and support obligations and enforcing support obligations; maintaining relationships with Department officials, other federal departments, State and tribal and local officials, and private organizations and individuals interested in the CSE program; coordinating and planning child support enforcement activities to maximize program effectiveness; outreach to the communities of faith and service, as well as access/visitation programs and advocacy interests and

approving all instructions, policies and publications issued by OCSE staff. The Office is responsible for Child Support Enforcement financial analysis and strategy development; overall grants and contracts planning and oversight, internal OCSE compliance operations; and the management of large-scale or high profile assistance activities involving multiple OCSE areas of responsibility.

KFB1. Office of Audit develops, plans, schedules and conducts periodic audits of CSE programs in accordance with audit standards promulgated by the Comptroller General. It is also responsible for liaison with other agencies on special law enforcement initiatives. The Division, headed by a Director reports directly to the Deputy Director/Commissioner, and will audit, at least once every three years (or more frequently in the case of a State which fails to meet the performance standards and the tests of the reliability of program data), the reliability of State financial and statistical data reporting systems used in calculating the paternity establishment percentage and the performance indicators used as the basis for the payment of performance based financial incentives to the State. These audits will examine the computer systems general and application controls and include in deputy testing of the data produced by the system to ensure that it is valid, complete and reliable. The Office will also conduct financial audits to determine whether federal and other funds made available to carry out the CSE programs are being appropriately expended, and properly and fully accounted for. These audits will also examine collections and disbursements of support payments for proper processing and accounting treatment.

The Office will also provide technical assistance to State and tribes in developing their self-assessment capabilities and implementing the annual reporting requirements contained in the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996.

In addition, the Office will also conduct other audits and examinations of program operations as may be necessary or requested by program officials for the purpose of improving the efficiency, effectiveness and economy of State, tribal, and local child support activities; develops consolidated reports for the Director and Deputy Director/Commissioner, OCSE based on findings; provides specifications for the development of audit regulations and requirements for audits of State and tribal CSE programs;

and coordinates and maintains effective liaison with the HHS Inspector General's Office and with the General Accounting Office.

The Office operates Project Save Our Children, a law enforcement liaison initiative which is a coalition of task forces, which currently covers 20 States and the District of Columbia. This initiative addresses interstate and tribal cases by: (1) Creating a formal partnership between CSE and the criminal justice system; (2) devising new ways to analyze and interpret information; and (3) making interstate and tribal child support enforcement a priority with the criminal justice community. At the heart of the task forces is a case screening unit and its information platform through which public and private databases are queried in an attempt to gather information concerning the whereabouts and assets of the non-custodial parents. Project Save Our Children's goal is to increase child support collections through the identification, investigation, and, when warranted, prosecution of flagrant, delinquent child support offenders. Project Save Our Children makes this possible by creating a nationwide, comprehensive, coordinated Health and Human Services/Justice Department response to unresolved interstate and tribal child support enforcement cases.

KFB. Office of the Deputy Commissioner. The Deputy Commissioner reports to the Deputy Director/Commissioner and assists the Commissioner in carrying out the responsibilities of OCSE, and provides leadership and direction to the Division of Consumer Services, Division of Management Services, Division of Planning, Research and Evaluation, Division of Policy, Division of Special Staffs, the Division of State, Tribal, Local Assistance, and the Office of Automation and Program Operations.

KFA-2. Division of Consumer Services provides direction and leadership for a variety of consumer affairs activities in support of the nationwide child support enforcement program. It provides advice on strategies and approaches to be used to improve public understanding of and access to OCSE programs and policies; develops and publishes informational materials and disseminates them through the National Reference Center and promotes "best" child support practices to the public through monthly publication of the *Child Support Report*. The Division advises the Deputy Director/Commissioner through the Deputy Commissioner of the impact of the child support enforcement program upon consumers and provides a focal point

for intergovernmental and consumer relations and consultation. This Division manages the access/visitation grants, the fatherhood initiative, and is responsible for the outreach to the communities of faith and service. The Division is also responsible for national electronic communications activities including disseminating information and operation of the OCSE Homepage on the internet and insuring that the information is placed thereon in a timely and accurate manner.

KFB2. The Division of Management Services manages the formulation and execution of the budgets for OCSE operated programs and for Federal administration of the CSE program; serves as the central control point for operational and long-range planning of the needs of the OCSE; plans for and coordinates the provision of staff development and training; provides support for OCSE's personnel administration, including staffing, employee and labor relations, performance management, and employee recognition; manages procurement planning and provides technical assistance regarding procurement; reviews and approves formula, entitlement, and block grant actions in conjunction with OCSE Offices and Divisions; manages OCSE-controlled space and facilities; performs manpower planning and administration; plans for, acquires, distributes, and controls OCSE supplies; provides mail and messenger services; maintains duplicating, fax, computer and computer peripheral equipment; supports and manages automation acquisition within OCSE; provides for health and safety; and oversees travel. It is also responsible for the day-to-day operational and administrative support services for the Office of Mandatory Grants and the Office of Grants Management, and other functions for OCSE. In addition, the Division reviews and manages clearance of Federal Register Notices and program announcements for OCSE, the Office of Family Assistance, the Office of Refugee Resettlement, the Office of Community Services, and the Office of Research and Evaluation.

KFA4. Division of Planning, Research and Evaluation is the principal advisor to the Deputy Commissioner on improving the effectiveness and efficiency of programs designed to make measurable improvements in the economic and social well-being of children and families.

The Division provides guidance, analysis, technical assistance, and oversight to CSE programs and across programs in ACF on strategic planning

aimed at measurable results; performance measurement; research and evaluation methodologies; demonstration testing and model development; statistical, policy and program analysis; synthesis and dissemination of research and demonstration findings; and application of emerging technologies to improve the effectiveness of programs and service delivery. The Division is also responsible for the collection, compilation, and analysis, and dissemination of data.

The Division oversees and manages the section 1115 social research programs relating to CSE, including: priority setting and analysis; processing waivers for OCSE; managing and coordinating major cross-cutting, leading-edge studies, collaborating with State and tribes, communities, foundations, professional organizations and others to promote the development of children, family focused services, parental responsibility, employment, and economic independence; and providing coordination.

KFB5. Division of Policy proposes and implements national policy for the CSE program and provides policy guidance and interpretations to State and tribes in developing and operating their programs according to federal law. It develops legislative proposals and regulations to implement new legislation, court decisions or directives from higher authority and provides comments on pending legislative proposals. The Division develops new State and Tribal plan preprint requirements and procedures for review and approval of State plans by the OCSE regional offices and prepares the justification for State plan disapproval actions. In consultation with the Director, Division of Planning, Research and Evaluation, negotiates with State and Tribes the five year national strategic plan. Coordinates with the Office of the General Counsel on pending departmental appeals.

KFA6. Division of Special Staffs. The Division of Special Staffs provides leadership to special high profile, high priority projects resulting from new legislation which expand the provision of child support services, such as employer outreach and relations, health industry enforcement, Hispanic outreach and welfare-to-work. In addition, the Division office has responsibility for implementation of the United States and tribes Central Authority for International Child Support and the new Native American/Tribal Child Support Enforcement Program. In coordination with the Division of Policy, the Division

conducts consultations and outreach to Tribes; reviews Tribal plans and works across OCSE Divisions in providing guidance, assistance and information to Tribes. The Division also works with the Office of Mandatory Grants in the issuance grants to Tribes.

KFB6. Division of State, Tribal, and Local Assistance, in concert with regional offices, provides information and assistance on CSE operations. It provides national direction and leadership for training and technical assistance activities and regional operations to increase CSE program effectiveness both at Federal and State/Tribal levels; develops guides and resource materials and serves as a clearinghouse for specialized program techniques for use by ACF regional offices and State and tribes; and ensures the transfer of best practices among State/tribes and local CSE enforcement agencies. The Division operates a national CSE training center which includes the operation of the National Electronic Resource System; provides logistical support for both training events and meetings; and monitors contracts with organizations affiliated with child support enforcement programs in the areas of training and technical assistance. The Division, through the Special Initiatives Branch, provides outreach and liaison services to a variety of special interest populations including (a) outreach to the homeless population, (b) interstate and tribal services, (c) intrastate (d) the judiciary, (e) law enforcement agencies, and (f) the military.

KFC. Office of Automation and Program Operations. The Office is headed by an Associate Commissioner who reports to the Deputy Director/Commissioner through the Deputy Commissioner and provides leadership and direction to the Division of State and Tribal Systems and Division of Federal Systems.

KFC5. Division of Federal Systems is responsible for the day-to-day operation of the Federal Parent Locator Service (FPLS), the Federal Tax Refund Offset Program, Project 1099, the IRS Full Collection Project, and the SSN Enumeration Verification System. The Division is also responsible for the design, development, implementation and operation of the Federal Case Registry (FCR) and the National Directory of New Hires (NDNH) within the expanded FPLS. It is responsible for monitoring contracts with vendors who provide automated systems support and quality assurance to these programs; working with vendors to define scope of work to be performed and by whom; negotiating interagency agreements; and

providing contract oversight. The Division, in consultation with the Division of State, Tribal, and Local Assistance, also provides technical assistance to State/tribal and local child support enforcement agencies. The Division provides guidance and expertise to State/Tribes concerning other State, interstate, tribal and national locate networks and sources. In addition, the Division works with the U.S. Department of State on passport revocation and other Federal agencies authorized to have access to NDNH and FCR data. The data is being used to: detect overpayments in the Supplemental Security Income and Disability programs; determine eligibility in the Earned Income Tax Credit (EITC) program; collect defaulted loans and grants made through the Department of Education's Student Loan Program; and, aid vital welfare reform research.

KFC4. Division of State and Tribal Systems reviews analyzes, and approves/disapproves State and tribal requests for Federal financial participation for automated systems development activities, which support the Child Support program. It provides assistance to State/Tribes in developing or modifying automation plans to conform to Federal requirements. It monitors approved State and tribal systems development activities; certifies State and tribal wide automated systems; conducts periodic reviews to assure State and tribal compliance with regulatory requirements applicable to automated systems supported by federal financial participation. It provides guidance to State and tribes on functional requirements for these automated information systems. It promotes interstate and tribal transfer of existing automated systems and provides assistance and guidance to improve ACF's programs through the use of automated systems.

KFD. Office of Grants Management. The Office of Grants Management is headed by a Director who reports to the Deputy Director/Commissioner and receives daily operational and administrative support services from the Director of Management Services. The Division provides management and technical administration for discretionary grants to the Office of Child Support Enforcement (OCSE), Office of Community Services (OCS), Office of Family Assistance (OFA) and Office of Planning, Research and Evaluation (OPRE); reviews, certifies and/or signs all discretionary grants; assures that all discretionary grants awarded by OCSE, OCS, OFA and OPRE conform with applicable statutes,

regulations, and policies; computes grantee allocations, prepares discretionary grant awards, ensures incorporation of necessary grant terms and conditions, and provides data in support of apportionment requests; prepares reports and analyses on the grantee's use of funds; maintains liaison and coordination with appropriate ACF and HHS organizations to ensure consistency between OCSE, OCS, OFA, and OPRE discretionary grant systems and the Department's grant payment systems; and provides technical assistance to regional components on discretionary grant operations and technical grants management issues; and performs audit resolutions activities for OCSE, OCS, OFA, and OPRE discretionary grant programs. On behalf of OCSE, OCS, OFA, and OPRE, coordinates and conducts liaison with the Department and other federal agencies on discretionary grants.

KFG. Office of Mandatory Grants. The Office of Mandatory Grants is headed by a Director who reports to the Deputy Director/Commissioner and receives daily operational administrative support services from the Director of Management Services. The Division provides management and technical administration of formula, entitlement and block grants administered by the following ACF program offices; OCSE; Office of Family Assistance (OFA); Office of Refugee Resettlement (ORR) and Office of Community Services (OCS). It assures that all formula, entitlement and block grant awards conform with applicable statutes, regulations, and policies; computes grantee allocations; prepares formula, entitlement and block grant awards; ensures incorporation of necessary grant terms and conditions, monitors grantee expenditures; analyzes financial needs under formula, entitlement and block grant programs; provides data in support of apportionment requests; prepares reports and analyses on the grantee's use of funds; maintains liaison and coordination with appropriate ACF and HHS organizations to ensure consistency between ACF formula, entitlement and block grant systems and the Department's grant payment systems; provides technical assistance to ACF program and regional components on formula, entitlement and block grant operations and technical grants management issues; and performs audit resolution activities for formula, entitlement and block grant programs. For OCSE and the other program offices served, provides liaison with the Department and other federal agencies on formula, entitlement and

block grants management and administration operational issues and activities.

Dated: January 19, 2001.

Olivia A. Golden,

Assistant Secretary for Children and Families.

[FR Doc. 01-2464 Filed 1-26-01; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96M-0311]

“PHS Guideline on Infectious Disease Issues in Xenotransplantation,” Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: On behalf of the U.S. Public Health Service (PHS), the Food and Drug Administration (FDA) is announcing the availability of a guideline entitled “PHS Guideline on Infectious Disease Issues in Xenotransplantation” dated January 19, 2001. This guideline was developed by the PHS to identify general principles for the prevention and control of infectious diseases associated with xenotransplantation that may pose a hazard to public health. The guideline is intended to provide general guidance to local review bodies evaluating proposed xenotransplantation protocols and to sponsors in developing xenotransplantation protocols, in preparing submissions to FDA and the Secretary’s Advisory Committee on Xenotransplantation, and in conducting xenotransplantation clinical trials. The guideline announced in this document finalizes the “Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation” announced in the **Federal Register** of September 23, 1996, as revised in response to comments.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the “PHS Guideline on Infectious Disease Issues in Xenotransplantation” dated January 19, 2001, to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 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 document may also be

obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the Fax Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guideline.

Submit written comments on the guideline to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Stephen M. Ripley, 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

On behalf of the PHS, FDA is announcing the availability of a document entitled “PHS Guideline on Infectious Disease Issues in Xenotransplantation” dated January 19, 2001. This guideline was jointly developed by agencies within the PHS of the Department of Health and Human Services (DHHS), including FDA, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the National Institutes of Health, as well as the DHHS Office of the Assistant Secretary for Planning and Evaluation. This guideline is intended to identify general principles for the prevention and control of infectious diseases associated with xenotransplantation that may pose a hazard to public health. It is intended to provide general guidance to local review bodies evaluating proposed xenotransplantation protocols and to sponsors in developing xenotransplantation protocols, in preparing submissions to FDA and the Secretary’s Advisory Committee on Xenotransplantation, and in conducting xenotransplantation clinical trials. Such clinical trials conducted within the United States are subject to regulation by FDA under the Public Health Service Act (42 U.S.C. 262, 264), and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

The finalized guideline announced in this document was revised based on public comments received in response to the “Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation” announced in the **Federal Register** of September 23, 1996 (61 FR49920), as well as on input from national and international conferences and workshops. The preamble to the final guideline provides a summary of the

major revisions and clarifications made to the draft guideline.

In the **Federal Register** of May 26, 2000 (65 FR 34196), FDA, on behalf of PHS, published a notice of the proposed reporting and recordkeeping requirements associated with the implementation of the guideline and provided an opportunity for public comment on the paperwork burden estimates for the guideline.

In the **Federal Register** of October 18, 2000 (65 FR 62359), FDA, on behalf of PHS, announced the submission of the reporting and recordkeeping burden estimates to the Office and Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guideline have been approved under OMB control number 0910-0456. This approval expires January 31, 2004. An agency may not conduct or sponsor, and a person is not obligated to respond to, a collection of information unless it displays a currently valid OMB control number.

This guideline represents PHS’ current thinking on certain infectious disease issues in xenotransplantation. It does not create or confer any rights for or on any person and does not operate to bind the PHS or the public. This guideline is not intended to set forth an approach that addresses all of the potential health hazards related to infectious disease issues in xenotransplantation nor to establish the only way in which the public health hazards that are identified in this document may be addressed. The PHS acknowledges that not all of the recommendations set forth within this document may be fully relevant to all xenotransplantation products or xenotransplantation procedures. Sponsors of clinical xenotransplantation trials are advised to confer with relevant authorities (FDA, other reviewing authorities, funding sources, etc.) in assessing the relevance and appropriate adaptation of the general guidance offered here to specific clinical applications.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guideline. 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 the brackets in the heading of this document. A copy of the guideline document and received comments are available for public examination in the Dockets