

mailing applications well in advance, when using all mail services, to ensure that the applications are received on or before the deadline time and date.

Applications hand carried by applicants, applicant couriers, or other representatives of the applicant or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m. at: OCS Operations Center, 1815 North Fort Myer Drive, Suite 300, Arlington, Virginia 22209 and labeled: Application for Compassion Capital Fund Coalition Program. Applicants are cautioned that express/overnight mail services may not always deliver as agreed.

ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF or the OCS Operations Center electronically will not be accepted regardless of date or time of submission and time of receipt.

Late applications. Applications that do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

Extension of deadlines. ACF may extend an application deadline for applicants affected by acts of God such as floods and hurricanes, when there is widespread disruption of the mail service, or for other disruptions of services, such as a prolonged blackout, that affect the public at large. A determination to waive or extend deadline requirements rest with ACF's Chief Grants Management Officer.

E. Paperwork Reduction Act of 1995 (Public Law 104-23)

Under the Paperwork Reduction Act of 1995, Public Law 104-13 the Department is required to submit to OMB for review and approval any reporting and record keeping requirements in regulations including program announcements. All information collections within this program announcement are approved under the following current valid OMB control numbers 0348-0043, 0348-0044, 034800040, 0348-0046, 0925-0418 and 0970-0139.

Public reporting burden for this collection is estimated to average 10 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection of information.

An agency may not conduct or sponsor and a person is not required to respond to, a collection of information

unless it displays a currently valid OMB control number.

Wade F. Horn,

Assistant Secretary for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0269]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infectious Disease Issues in Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information contained in the Public Health Service (PHS) guideline entitled "PHS Guideline on Infectious Disease Issues in Xenotransplantation" dated January 19, 2001.

DATES: Submit written or electronic comments on the collection of information by September 8, 2003.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecommments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the

Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Infectious Disease Issues in Xenotransplantation (OMB Control Number 0910-0456)—Extension

The statutory authority to collect this information is provided under sections 351 and 361 of the PHS Act (42 U.S.C. 262 and 264) and the provisions of the Federal Food, Drug, and Cosmetic Act that apply to drugs (21 U.S.C. 301 *et seq.*). The PHS guideline recommends procedures to diminish the risk of transmission of infectious agents to the xenotransplantation product recipient and the general public. The PHS guideline is intended to address public health issues raised by xenotransplantation, through identification of general principles of prevention and control of infectious diseases associated with xenotransplantation that may pose a hazard to the public health. The collection of information described in this guideline is intended to provide general guidance to sponsors in: (1) The development of xenotransplantation clinical protocols, (2) the preparation of submissions to FDA, and (3) the