

All profiles issued as "Drafts for Public Comment" represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 17, 2003.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

Tribal Consultation (Listening Sessions) With American Indian/Alaskan Native/Native Hawaiian Representatives

SUMMARY: The Department of Health and Human Services policy on consultation with American Indian/Alaska Native (AI/AN) Governments and Organizations requires each Operating Division to meet with AI/AN Tribal Representatives. The Administration on Aging (AoA) will call three Tribal Listening Sessions that comply with the Department's tribal consultation policy and the Older Americans Act (OAA). The listening sessions will be held in conjunction with OAA Title VI training and technical assistance meetings in 2003 and 2004.

The Tribal Listening Sessions will give AI/AN Tribal representatives, Native Hawaiian representatives, Title VI Directors, and AI/AN elders an opportunity to discuss Native American elder issues. The Administration on Aging is interested in the following critical issues:

What can the Aging Services Network do to empower older people and their families to make the best decisions about their care options? How can tribes build on the early success of the Native American Family Caregiver Support Program and expand access to information, make services more consumer-friendly, and allow caregivers more choices? What innovations are occurring at the Tribe, State and local level related to access and service delivery that could serve as models for other Tribes and communities across the country?

Anyone interested in testifying must pre-register to obtain a time slot. To accommodate as many speakers and diverse opinions as possible, each person will have a maximum of 10 minutes. AoA will accept a copy of written remarks at the time of the Tribal Listening Session.

DATES: The Tribal Listening Sessions are from 1 to 4 pm on the following dates and locations:

- October 29, 2003—Reno/Sparks, Nevada
- Feb. 25, 2004—Phoenix, Arizona
- April 28, 2004—Rapid City, South Dakota

FOR FURTHER INFORMATION AND TO REGISTER CONTACT:

Kaufmann and Associates at 425 West 1ST Avenue, Spokane, WA 99201, phone: (509) 747-4994, fax: (509) 747-5030. These are not toll-free numbers. Electronic mail address: info@olderindians.org

If you are unable to attend but wish to provide comments or Tribal Resolutions, these may be faxed to Kauffman & Associates, Inc at (509) 747-5030.

In accordance with the provisions of the Americans with Disabilities Act (ADA), it is requested that any special assistance requirements be requested when registering for a Tribal Listening Session.

Dated: October 20, 2003.

Josefina G. Carbonell,

Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0269]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infectious Disease Issues in Xenotransplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by November 24, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 under 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 conduct of xenotransplantation clinical trials. Also, the collection of information will help ensure that the sponsor maintains important information in a cross-referenced system that links the relevant records of the xenotransplantation product recipient, xenotransplantation product, source animal(s), animal procurement center, and significant nosocomial exposures. The PHS guideline describes an occupational health service program for the protection of health care workers involved in xenotransplantation procedures, caring for xenotransplantation product recipients, and performing associated laboratory