and other *in vitro* alternative test methods be considered prior to *in vivo* pyrogenicity testing, where determined appropriate for a specific testing situation.

NICEATM also announces availability of the final *ICCVAM Background Review Document: Validation Status of Five In Vitro Test Methods Proposed for Assessing Potential Pyrogenicity of Pharmaceuticals and Other Products* (NIH Publication 08–6391). The final background review document (BRD) provides the data and analyses used to assess the current validation status of these five *in vitro* test methods.

The ICCVAM TMER and supporting BRDs have been forwarded to U.S. Federal agencies for regulatory and other acceptance consideration, where applicable. Responses received will be posted on the NICEATM–ICCVAM Web site.

ADDRESSES: Electronic copies of the ICCVAM TMER and final BRD are available from the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov* or by contacting NICEATM (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov* Courier address: NICEATM, NIEHS, 79 T.W. Alexander Drive, Building 4401, Room 3128, Research Triangle Park, NC 27709.

SUPPLEMENTARY INFORMATION:

Background

In 2005, the European Centre for the Validation of Alternative Methods (ECVAM), a unit of the Institute for Health and Consumer Protection at the European Commission's Joint Research Centre, submitted BRDs for five *in vitro* pyrogen test methods proposed as replacements for the RPT to ICCVAM for formal evaluation of their scientific validity for regulatory testing purposes. ICCVAM unanimously agreed that the five submitted *in vitro* pyrogen test methods should have high priority for evaluation. On December 16, 2005, NICEATM published a **Federal Register** notice (Vol. 70, No. 241, pages 74833–74834), requesting public comments on the appropriateness and relative priority of convening an independent peer review panel (Panel) to evaluate the validation status of the five *in vitro* pyrogen test methods, the nomination of scientists to serve on the Panel, and the submission of data from *in vivo* and *in vitro* pyrogenicity testing. Based on the ECVAM BRDs as well as data and information submitted in response to the aforementioned **Federal Register** notice, NICEATM subsequently compiled a comprehensive draft BRD on the five *in vitro* pyrogen test methods and released it for public comment on December 12, 2006 (Vol. 71, No. 238, pages 74533–74534).

On February 6, 2007, NICEATM and ICCVAM convened a Panel to review the ICCVAM draft BRD for errors and omissions and to evaluate the validation status of the five *in vitro* pyrogen test methods. The Panel also reviewed the extent that the information contained in the ICCVAM draft BRD supported the ICCVAM draft test method recommendations for proposed test method uses, standardized protocols, test method performance standards, and additional studies. The Panel considered public comments made at the Panel meeting, as well as public comments submitted in advance of the meeting, before concluding their deliberations. NICEATM made the Panel's report available in May 2007 (Vol. 72, No. 89, pages 26395–26396). The ICCVAM draft BRD and draft recommendations, the Panel's report, and all public comments were made available to the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) for review and comment at their meeting on June 12, 2007 (Vol. 72, No. 83, pages 23831–23832).

ICCVAM considered the Panel's report, all public comments, and the comments of SACATM in finalizing its recommendations on the use of these five *in vitro* test methods proposed for assessing potential pyrogenicity of pharmaceuticals and other products. The ICCVAM TMER includes the ICCVAM recommendations on uses and limitations for each test method, standardized protocols, future studies, and the development of performance standards, as well as the Panel's report and **Federal Register** notices. The final BRD, which provides the supporting documentation for this report, is available as a separate document. ICCVAM forwarded the ICCVAM TMER and the supporting final BRD to U.S. Federal agencies for consideration, in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–3). Agency responses to the ICCVAM test method recommendations will be made available on the NICEATM–ICCVAM Web site as they are received.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found at *http://www.iccvam.niehs.nih.gov*.

SACATM was established January 9, 2002 (Vol. 67, No. 49, page 11358), and is composed of scientists from the public and private sectors. SACATM provides advice to the Director of the NIEHS, to ICCVAM, and to NICEATM regarding the statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/go/167*.

Dated: November 7, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–27790 Filed 11–21–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership on the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science.

ACTION: Notice.

Authority: 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The Office for Human Research Protections (OHRP), a program

office in the Office of Public Health and Science, Department of Health and Human Services (HHS), is seeking nominations of qualified candidates to be considered for appointment as members of the Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP provides advice and recommendations to the Secretary, HHS, and the Assistant Secretary for Health on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. SACHRP was established by the Secretary, HHS, on October 1, 2002. OHRP is seeking nominations of qualified candidates to fill two positions on the Committee membership that will be vacated in June of 2009.

DATES: Nominations for membership on the Committee must be received no later than January 23, 2009.

ADDRESSES: Nominations should be mailed or delivered to Dr. Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200; Rockville, MD 20852. Nominations also may be sent via e-mail to *sachrp@hhs.gov* or via facsimile at 240–453–6909.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, Executive Director, SACHRP, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, telephone: 240–453–8141. A copy of the Committee charter and list of the current members can be obtained by contacting Ms. Gorey, accessing the SACHRP Web site at *http://www.hhs.gov/ohrp/sachrp,* or requesting via e-mail at *sachrp@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Committee provides advice on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. Specifically, the Committee provides advice relating to the responsible conduct of research involving human subjects with particular emphasis on special populations such as neonates and children, prisoners, the decisionally impaired, pregnant women, embryos and fetuses, individuals and populations in international studies, investigator conflicts of interest and populations in which there are individually identifiable samples, data, or information.

In addition, the Committee is responsible for reviewing selected ongoing work and planned activities of the OHRP and other offices/agencies within HHS responsible for human subjects protection. These evaluations may include, but are not limited to, a review of assurance systems, the application of minimal research risk standards, the granting of waivers, education programs sponsored by OHRP, and the ongoing monitoring and oversight of institutional review boards and the institutions that sponsor research.

Nominations: The Office for Human Research Protections is requesting nominations to fill two positions for voting members of SACHRP. The two positions will become vacant in June of 2009. Nominations of potential candidates for consideration are being sought from a wide array of fields, including, but not limited to: public health and medicine, behavioral and social sciences, health administration, and biomedical ethics.

To qualify for consideration of appointment to the Committee, an individual must possess demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research.

The individuals selected for appointment to the Committee can be invited to serve a term of up to four years. Committee members receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business in the interest of the Committee.

Nominations should be typewritten. The following information should be included in the package of material submitted for each individual being nominated for consideration: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.* , specific attributes which qualify the nominee for service in this capacity), and a statement that the nominee is willing to serve as a member of the Committee; (2) the nominator's name, address and daytime telephone number, and the home and/or work address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae. Federal employees should not be nominated for consideration of appointment to this Committee.

The Department makes every effort to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that individuals from a broad representation of geographic areas, women and men, ethnic and minority groups, and the disabled are given consideration for membership on HHS Federal advisory committees. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Documentation must be included in the nomination to indicate that the nominated individual is willing to serve as a member of SACHRP. Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of SACHRP.

Dated: November 18, 2008.

Jerry Menikoff,

Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. E8–27851 Filed 11–21–08; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: Indian Tribes, Tribal Organizations or Tribal Consortia Letter of Intent to Operate a Title IV–E Program.

OMB No.: New Collection.

Description: The Fostering Connections to Success and Increasing Adoptions Act of 2008 (Pub. L. 110–351) added section 479B to the Social Security Act (the Act), which allows Indian Tribes the option to apply to the Secretary to receive Federal funding to support the administration of their own foster care, adoption assistance and relative guardianship programs under title IV–E of the Act. The law also amended the Act at section 476(c)(2)(ii) to allow Indian Tribes to receive one-time development grants of up to $300,000 to be used to offset the cost of developing a title IV–E plan to carry out the requirements of section 479B of the Act, and required ACF to provide technical assistance and