DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Correction—National Advisory Council for Healthcare Research and Quality; Request for Nominations for Public Members

The original notice was published in the **Federal Register** on May 6, 2004 under Volume 69, Number 88, Pages 25391–25392 *(http://a257.g.akamaitech.net/7/257/2422/14mar* 20010800/edocket.access.gpo.gov/2004/04–10283.htm). With this notice, the Agency for Healthcare Research and Quality (AHRQ) is informing the public that the correct contact numbers are: Phone #: 301–427–1330 and Fax # 301–427–1341.

Dated: May 13, 2004.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Opportunity To Collaborate in the Evaluation of Topical Microbicides To Reduce Sexual Transmission of Human Immunodeficiency Virus (HIV)

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Opportunities for collaboration for evaluation of topical microbicides.

The Centers for Disease Control and Prevention (CDC), National Center for HIV, STD, and TB Prevention (NCHSTP), Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP–SE), Epidemiology Branch (EpiBr), announces an opportunity for collaboration to evaluate the safety and preliminary efficacy of topical microbicides designed for vaginal and/or rectal application to reduce HIV transmission. These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in women and men.

SUMMARY: The Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP–SE) of the National Center of HIV, STD, and TB Prevention (NCHSTP) at the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (DHHS) seeks one or more pharmaceutical, biotechnical, or other companies that hold a proprietary position on agents which may be useful as microbicides to prevent sexual transmission of HIV infection. The selected company and CDC will execute an Agreement under which the company will provide a product for CDC to study the product's safety and preliminary efficacy as a topical microbicide. Initial studies will include in-vitro assays and may include macaque studies. Agents will be selected for phase I and phase II trials in women and men based upon data obtained in the CDC studies as well as other available published and unpublished safety and efficacy data. Each collaboration would have an expected duration of one (1) to five (5) years. The goals of the collaboration include the timely development of data to further the identification and commercialization of effective topical microbicides and the rapid publication of research findings to increase the number of HIV prevention technologies proven effective and available for use.

Confidential proposals, preferably 10 pages or less (excluding appendices), are solicited from companies with patented or licensed agents which have undergone sufficient preclinical testing to be prepared to submit an Investigational New Drug (IND) application to the FDA within six months of submitting the proposal.

DATES: This Notice will be open indefinitely.

ADDRESSES: Formal proposals should be submitted to Carmen Villar, Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–5259, (office) 404–639–6130; Fax: 404–639–6127; e-mail: *CVillar@cdc.gov.* Scientific questions should be addressed to Lisa A. Grohskopf, MD, MPH, Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6116, (office) 404–639–6146; Fax: 404–639–6127; e-mail: *lkg6@cdc.gov.* Inquiries directed to ''Agreement'' documents related to participation in this opportunity should be addressed to Thomas E. O'Toole, MPH, Deputy Director, Technology Transfer Office, CDC, 1600 Clifton Road, Mailstop K–79, Atlanta, GA 30333; Phone: (direct) 770–488–8611, (office) 770–488–8607; Fax: 770–488–8615; e-mail: *TEO1@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Technology Available

One mission of the Epidemiology Branch (EpiBr) of DHAP–SE/NCHSTP is to develop and evaluate biomedical interventions to reduce HIV transmission. To this end, the EpiBr is establishing contracts to conduct phase I and phase II trials of topical microbicides. EpiBr also funds research in the Division of AIDS, STD, and TB Laboratory Research (DASTLR) of the National Center for Infectious Diseases (NCID) at CDC and with external laboratories to conduct macaque studies and in-vitro studies in support of human microbicide trials. The goal of these efforts is to provide scientific and technical expertise and key resources for the evaluation of topical microbicides through late preclinical, phase I and phase II safety and phase II efficacy clinical trials.

Technology Sought

EpiBr now seeks potential collaborators having licensed or patented agents for use as vaginal and/or rectal microbicides which:

(1) Have laboratory or animal model evidence of anti-HIV activity;

(2) Have been formulated for vaginal or rectal application;

(3) Are not entering phase III clinical trial in the next 12 months;

(4) Have sufficient preclinical data to submit an IND application within approximately six months following submission of proposal; and

(5) Have manufacturing arrangements for production of clinical trial-grade product (and applicator if necessary) under Good Manufacturing Process (c–GMP) standards.

NCHSTP and Collaborator Responsibilities

The NCHSTP anticipates that its role may include, but not be limited to, the following:

(1) Providing intellectual, scientific, and technical expertise and experience to the research project;

(2) Planning and conducting preclinical (in-vitro and in-vivo) research studies of the agent and interpreting results;

(3) Publishing research results;

(4) Depending on the results of these preclinical investigations, NCHSTP may elect to conduct additional research with macaques to evaluate safety and/or efficacy proof-of-concept; and

(5) Depending on the results of preclinical and/or macaque studies and FDA approval, NCHSTP may elect to conduct phase I/II clinical trials of the agent.