| Anticipated 2004–2007 projects | Number of respondents | Number of responses per respondent | Average burden per response (in hours) |
|---|---|---|---|
| (2) Behavioral Risk Factor Surveillance System Survey (BRFSS) | 50 | 1 | 1.25 |
| (3) Healthy People 2010 (HP 2010) | 50 | 1 | 1.25 |
| (4) National Survey of Family Growth (NSFG) | 50 | 1 | 1.25 |
| (5) Pregnancy Risk Assessment Monitoring System (PRAMS) | 50 | 1 | 1.25 |
| (6) National Health and Nutrition Examination Survey (NHANES) | 50 | 1 | 1.25 |
| (7) Other questionnaire testing: | | | |
| 2004 | 100 | 1 | 1.25 |
| 2005 | 100 | 1 | 1.25 |
| 2006 | 100 | 1 | 1.25 |
| (8) Perceptions of Quality of Life project | 80 | 1 | 1.25 |
| (9) Perceptions of Confidentiality Project | 50 | 1 | 1.25 |
| (10) Perception of Statistical Maps Project | 50 | 1 | 1.25 |
| (11) General Methodological Research | 100 | 1 | 1.25 |
| Pilot Household Interviews: | | | |
| 2004 NHIS Modules | 50 | 1 | 1.25 |
| 2005 NHIS Modules | 50 | 1 | 1.25 |
| 2006 NHIS Modules | 50 | 1 | 1.25 |
| Focus Groups (10 groups of 10 for three years) | 300 | 1 | 1.50 |

Dated: December 8, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control And Prevention.*

[FR Doc. 03–31187 Filed 12–17–03; 8:45 am]

**BILLING CODE 4163–18–P**

## 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 (DHHS).

**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.

The NCHSTP anticipates that the role of the successful collaborator(s) will include the following:

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

(2) Participating in the planning of research studies, interpretation of research results, and as appropriate, joint publication of conclusions;

(3) Providing NCHSTP access to necessary proprietary technology and/or data in support of the research activities; and

(4) Providing NCHSTP clinical grade (c-GMP) agent for use in preclinical and clinical studies covered in this collaboration.

Other contributions may be necessary for particular proposals.

**Selection Criteria**

In addition to evidence of the ability to fulfill the roles described above, proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

(1) Data on the in-vitro anti-HIV activity of the agent;

(2) Animal and other data on the safety of the agent when applied to mucosal surfaces;

(3) Data on the effects of the agent on vaginal and/or rectal commensal microbial organisms; and

(4) Data on the in-vitro activity of the agent against other sexually transmitted organisms.

Dated: December 11, 2003.

**Joseph R. Carter,**

*Deputy Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 03–31186 Filed 12–17–03; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Advisory Committee Information Hotline

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that we have revised the Advisory Committee Information Hotline (the hotline). The hotline provides the public with access to the most current information available on FDA advisory committee meetings. This notice supersedes all previously published announcements of FDA's Advisory Committee Information Hotline.

**FOR FURTHER INFORMATION CONTACT:** Theresa L. Green, Committee Management Officer (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

**SUPPLEMENTARY INFORMATION:** The Advisory Committee Information Hotline can be accessed by dialing 1–800–741–8138 or 301–443–0572. The advisory committee meeting information and information updates can also be accessed via FDA's Advisory Committee calendar at *http://www.fda.gov/oc/advisory/accalendar/accalendar.html*.

Each advisory committee is assigned a 10-digit number. This 10-digit number will appear in each individual notice of meeting. The public can obtain information about a particular advisory committee meeting by using the committee's 10-digit number. Information on the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made. The following is a list of each advisory committee's 10-digit number to be used when accessing the hotline.

| ADVISORY COMMITTEE | NUMBER |
|---|---|
| OFFICE OF THE COMMISSIONER | |
| Science Board to the FDA | 3014512603 |
| CENTER FOR BIOLOGICS EVALUATION AND RESEARCH | |
| Allergenic Products Advisory Committee | 3014512388 |
| Biological Response Modifiers Advisory Committee | 3014512389 |
| Blood Products Advisory Committee | 3014519516 |
| Transmissible Spongiform Encephalopathies Advisory Committee | 3014512392 |
| Vaccines and Related Biological Products Advisory Committee | 3014512391 |
| CENTER FOR DRUG EVALUATION AND RESEARCH | |
| Anesthetic and Life Support Drugs Advisory Committee | 3014512529 |
| Anti-Infective Drugs Advisory Committee (Peds SubC) | 3014512530 |
| Antiviral Drugs Advisory Committee | 3014512531 |
| Arthritis Advisory Committee | 3014512532 |
| Cardiovascular and Renal Drugs Advisory Committee | 3014512533 |