Dated: June 22, 2001.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–16247 Filed 6–27–01; 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 Transmission of Human Immunodeficiency Virus (HIV) Among Men Who Have Sex With Men (MSM)

AGENCY: Centers for Disease Control and Prevention, 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 (EpiB), has an opportunity for collaboration to evaluate the safety and preliminary efficacy of topical microbicides for rectal application to reduce HIV transmission. These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in MSM.

SUMMARY: The Division of HIV/AIDS Prevention-Surveillance and Epidemiology (DHAP–SE) of the National Center for 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, biotechnological, or other companies who hold a proprietary position on microbicides developed for vaginal use that are ready for phase III trials. The selected company and CDC would execute an ''Agreement'' to evaluate the company's microbicides for safety and acceptability of topical microbicides designed for vaginal application to reduce HIV transmission when applied to the rectal mucosa. These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in MSM. Each collaboration would have an expected duration of two (2) 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 by MSM as well has heterosexual men and women.

Confidential proposals, preferably 10 pages or less (excluding appendices), are solicited from companies with patented or licensed agents which have undergone sufficient clinical testing to be: (1) Currently under an IND approved by the Food and Drug Administration (FDA); (2) have completed at least one phase I and one phase II trial for vaginal application of the microbicide as of December 31, 2001; and (3) be planning to begin a phase III trial for vaginal use which is anticipated to begin enrollment prior to December 31, 2002.

DATES: Formal proposals must be submitted no later than July 30, 2001.

ADDRESSES: Formal proposals should be submitted to Jeff Efird, MPA, Epidemiology Branch, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6136, (office) 404–639–6130; Fax: 404–639–6127; e-mail: *JLE1@cdc.gov*. Scientific questions should be addressed to Dawn K. Smith, MD., Epidemiology Branch, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6165, (office) 404–639–6146; Fax: 404–639–6127; e-mail: *Dsmith1@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 E–67, Atlanta, GA 30333; Phone: (direct) 404–639–6270, (office) 404–639–6270; Fax: 404–639–6266; e-mail: *TEO1@cdc.gov*.

SUPPLEMENTARY INFORMATION:

Technology Available

One mission of the Epidemiology Branch 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, phase II, and proof-of-concept clinical trials.

Technology Sought

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

(1) Will have at least one phase I and one phase II trial for vaginal use completed by December 31, 2001;

(2) Will have a phase III trial for vaginal use planned to begin enrollment prior to December 31, 2002;

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

(4) Are willing to provide a formulation and dosage appropriate for rectal application.

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, human, and in-vitro data on the safety of the agent when applied to mucosal surfaces;

(3) Data on the effects of the agent on rectal mucosa (if available); and

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

Dated: June 22, 2001.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention.

[FR Doc. 01–16243 Filed 6–27–01; 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 Heterosexual Transmission of Human Immunodeficiency Virus (HIV)

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

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), has an opportunity for collaboration to evaluate the safety and preliminary efficacy of topical microbicides designed for vaginal application to reduce HIV transmission. These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in heterosexual 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, biotechnological, or other companies who hold a proprietary position on microbicides that are ready for phase I/phase II trials. The selected company and CDC will execute an ''Agreement'' to evaluate the company's microbicides for safety and preliminary efficacy of topical microbicides designed for vaginal application to reduce HIV transmission.

These evaluations will include in-vitro assays, macaque studies, and phase I/phase II trials in heterosexual women and men. Each collaboration would have an expected duration of two (2) 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 either (1) currently under an IND application approved by the Food and Drug Administration (FDA) or (2) prepared to submit an IND application to the FDA by December 31, 2001.

DATES: Formal proposals must be submitted no later than July 30, 2001.

ADDRESSES: Formal proposals should be submitted to Jeff Efird, MPA, Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6136, (office) 404–639–6130; Fax: 404–639–6127; e-mail: *JLE1@cdc.gov.* Scientific questions should be addressed to Dawn K. Smith, MD., Epidemiology Branch, Division of HIV/AIDS Prevention—Surveillance and Epidemiology, NCHSTP, CDC, 1600 Clifton Road, Mailstop E–45, Atlanta, GA 30333; Phone: (direct) 404–639–6165, (office) 404–639–6146; Fax: 404–639–6127; e-mail: *Dsmith1@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 E–67, Atlanta, GA 30333; Phone: (direct) 404–639–6270, (office) 404–639–6270; Fax: 404–639–6266; e-mail: *TEO1@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Technology Available

One mission of the Epidemiology Branch 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, phase II, and proof-of-concept clinical trials.

Technology Sought

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

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

(2) Have been formulated for vaginal application;

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

(4) Have an IND and are currently in phase I clinical trial or have not yet submitted an IND application but have sufficient preclinical data to do so by December 31, 2001; and

(5) Have manufacturing arrangements for production of clinical trial-grade product (an 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