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.

[FR Doc. 04–11372 Filed 5–19–04; 8:45 am]

BILLING CODE 4160–90–M

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.

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: May 14, 2004.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 04–11402 Filed 5–19–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0221]

Medicare Prescription Drug, Improvement, and Modernization Act of 2003; Study on Making Prescription Pharmaceutical Information Accessible for Blind and Visually-Impaired Individuals; Establishment of Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a docket to receive information and comments on certain issues related to the accessibility of pharmaceutical information to blind and visually-impaired individuals. This action is intended to ensure that there is a venue for information and comments to be communicated to the agency for consideration in a study on making prescription drug information accessible for blind and visually-impaired individuals, which was mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Medicare Modernization Act).

DATES: The agency encourages interested parties to submit information and comments by June 21, 2004.

ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Poppy Kendall, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, e-mail: *poppy.kendall@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On December 8, 2003, President Bush signed the Medicare Modernization Act (Public Law 108–173). Section 107(f) of this legislation requires that the Secretary of Health and Human Services undertake a study on how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually-impaired individuals. The legislation requires that the study ''include a review of existing and emerging technologies, including assistive technology, that makes essential information on the content and prescribed use of pharmaceutical medicines available in a usable format for blind and visually-impaired individuals.''

II. Request for Comments

To assist in this effort, we are asking for public comment on the following issues:

A. Information About the Population of Interest:

1. What is known about the population of people who are blind and visually-impaired in the United States (e.g., information on age of onset; cause of impairment (e.g., congenital defect versus disease-related versus injury); extent and type of impairment; association between visual impairment and age, hearing loss, comorbidities, health outcomes, socioeconomic status, health literacy, and adaptive learning capabilities)?

2. Is there an appropriate way to divide this population into subpopulations to better evaluate needs and beneficial technologies?

B. Information About the Use of Prescription Medication Information By People Who Are Blind or Visually-Impaired:

1. How do people who are blind and visually-impaired currently get their prescription drug information?

2. What aspects of visual impairment are important to addressing the issue of access to prescription drug information? What other factors (see examples listed in Question #A1) might be important to addressing this issue?

3. How can essential drug information be effectively communicated to people who are blind or visually impaired?

4. Are there data associating medication errors with blindness? With visual impairment? What types of medication errors are most common among people who are blind or visually impaired?

C. Information About Existing and Emerging Technologies (Including Internet-based Information Sources):

1. What assistive technologies are currently used by people who are blind or visually-impaired? In what setting?

2. What proportion of people who are blind and visually-impaired currently use these technologies? Are there specific characteristics (see examples listed in Question #A1) of this ''user'' population that distinguish them from blind and visually-impaired individuals who do not use these technologies?

3. Are there data on the effectiveness of these technologies?

4. Do these technologies contribute to an increase or decrease in medication errors reported amongst people who are blind or visually impaired?

5. What is the cost of these technologies?

6. Who are the primary purchasers of these technologies? Is use of these technologies currently subsidized by any government or private program?

7. What are barriers to use of these assistive technologies?

8. What is the practicability of these assistive technologies?

9. How do people who are blind or visually-impaired learn of these technologies?

9a. What are the most effective resources for conveying information about these assistive technologies to blind and visually impaired individuals.

10. Are there emerging technologies that show promise? If so, what is the