

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phase II trials in women and men based upon data obtained in the CDC studies as well as other available published and unpublished safety and efficacy data.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 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 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 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 (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.

Joseph R. Carter,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-460]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send

comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare Participating Physician or Supplier Agreement, CMS-460; *Form No.:* CMS-460 (OMB# 0938-0373); *Use:* The CMS-460 is completed by nonparticipating physicians and supplier if they choose to participate in Medicare Part B. By signing the agreement, the physician or supplier agrees to take assignment on all Medicare claims. To take assignment means to accept the Medicare allowed amount as payment in full for the services they furnish and to charge the beneficiary no more than the deductible and coinsurance for the covered service. In exchange for signing the agreement, the physician or supplier receives a significant number of program benefits not available to nonparticipating physicians and suppliers. The information is needed to know to whom to provide these benefits.; *Frequency:* Once, unless re-enrolled; *Affected Public:* Business or other for-profit, and Individuals or Households; *Number of Respondents:* 6,250; *Total Annual Responses:* 6,250; *Total Annual Hours:* 1,563. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Dawn Willingham, CMS-460, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 7, 2002.

John P. Burke III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-R-257]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Medicare + Choice Disenrollment Form to original Medicare; *Form No.:* CMS-R-257 (OMB# 0938-0741); *Use:* Section 4001 of the Balanced Budget Act of 1997 amended the Social Security Act to add Section 1851; including 1851(c) (1) which required the establishment of a procedure and form to make and change Medicare + Choice elections, which include disenrollment. In addition, BBA of 1997 also required information be provided to beneficiaries to make better informed choices. Certain information is needed from the beneficiary in order to process the disenrollment action as a change of election.; *Frequency:* On

occasion; *Affected Public:* Individuals or Households, Business or other for-profit, federal government, not-for-profit institutions; *Number of Respondents:* 50,000; *Total Annual Responses:* 50,000; *Total Annual Hours:* 3,300.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 7, 2002.

John P. Burke III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-R-267]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper