

to be used to determine whether the test could be used in the diagnosis of syphilis and/or screening for syphilis in the United States.

Confidential proposals, preferably six pages or less (excluding appendices), are solicited from companies who have a product that is suitable for commercial distribution.

**DATES:** Formal proposals must be submitted no later than September 24, 2001.

**ADDRESSES:** Formal proposals should be submitted to Candice Nowicki-Lehnherr, Division of STD Prevention, NCHSTP, CDC, 1600 Clifton Road, Mailstop E-05 Atlanta, GA 30333; Phone 404-639-8264; Fax 404-639-8608; e-mail: [cxm1@cdc.gov](mailto:cxm1@cdc.gov). Scientific questions should be addressed to Madeline Sutton, MD, Division of STD Prevention, NCHSTP, CDC, 1600 Clifton Road, Mailstop E-05, Atlanta, GA 30333; Phone: 404-639-8368; Fax: 404-639-8610; e-mail [msutton@cdc.gov](mailto:msutton@cdc.gov).

#### SUPPLEMENTARY INFORMATION

##### Technology Sought

One mission of the Division of STD Prevention/NCHSTP is to develop and evaluate biomedical interventions to reduce syphilis. To this end, the Surveillance and Epidemiology Branch is seeking rapid diagnostic tests for syphilis that are suitable for commercial distribution and that are simple, tests that can be performed in 30 minutes or less by persons with minimal training.

##### NCHSTP and Collaborator Responsibilities

The NCHSTP role may include, but will not be limited to, the following:

- (1) Providing scientific, and technical expertise needed for the research project;
- (2) Planning and conducting research studies of the diagnostic tests and interpreting results; and
- (3) Publishing research results.

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

- (1) Providing tests that can be used in the evaluation; and
- (2) Providing NCHSTP access to necessary data in support of the research activities.

##### Selection Criteria

Proposals submitted for consideration should address, as best as possible and to the extent relevant to the proposal, each of the following:

- (1) Data available on the performance of the tests in different stages of syphilis and in the absence of syphilis;
- (2) Information on the technology used for the test;

(3) Information on the time required to perform the test, whether the test is performed on whole blood, sera, plasma or saliva and the steps involved in performing the test; and

(4) Interest by the company to seek FDA approval and market the test in the United States.

Dated: August 17, 2001.

**Joseph R. Carter,**

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

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-R-216]

#### Agency Information Collection Activities: Submission For OMB Review; Comment Request

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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the 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:* Procedures for Advisory Opinions Concerning Physician Referrals and Supporting Regulations in 42 CFR 411.370 through 411.389; *Form No.:* CMS-R-216 (OMB# 0938-0714); *Use:* Section 4314 of Public Law 105-33, in establishing section 1877(g)(6) of the Act, requires the Department to provide advisory opinions to the public regarding whether a physician's referrals for certain designated health services are prohibited under the other provisions in section 1877 of the Act. These

regulations provide the procedures under which members of the public may request advisory opinions from CMS. Because all requests for advisory opinions are purely voluntary, respondents will only be required to provide information to us that is relevant to their individual requests; *Frequency:* On occasion; *Affected Public:* Not-for-profit institutions, business or other for-profit, and individuals and households; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 2,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access CMS's web site address at <http://www.hcfa.gov/regs/prduct95.htm>, or E-mail your request, including your address and phone number, to [Paperwork@hcfa.gov](mailto: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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 1, 2001.

**John P. Burke III,**

*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

### Food and Drug Administration

[Docket No. 00C-1444]

#### FEM, Inc.; Withdrawal of Color Additive Petition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a color additive petition (CAP 0C0272) proposing that the color additive regulations be amended to eliminate the limitation on the amount of silver used as a color additive in fingernail polish.

**FOR FURTHER INFORMATION CONTACT:** James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS-