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.* 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.*

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 preformed 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.

[FR Doc. 01–21271 Filed 8–22–01; 8:45 am]

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/prdact95.htm, or E-mail your request, including your address and phone number, 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 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.

[FR Doc. 01–21323 Filed 8–22–01; 8:45 am]

BILLING CODE 4120–03–P

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–

215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3078.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 18, 2000 (65 FR 50543), FDA announced that a color additive petition (CAP 0C0272) had been filed by FEM, Inc., 1521 Laguna St., # 210, Santa Barbara, CA 93101. The petition proposed to amend the color additive regulations in § 73.2500 *Silver* (21 CFR 73.2500) to eliminate the limitation on the amount of silver used as a color additive in fingernail polish. FEM, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)).

Dated: August 13, 2001.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–21245 Filed 8–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 12, 2001, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Thomas H. Perez, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301– 827–6758, e-mail at PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider the safety and efficacy of Activated Protein C (human, recombinant, human kidney cells, new biologic license application (BLA) 125029), Eli Lilly & Co. for the treatment of severe sepsis.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 4, 2001. Oral presentations from the public will be scheduled on September 12, 2001, between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 16, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–21284 Filed 8–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0278]

Draft ''Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research '' dated August 2001. The draft guidance document discusses Type V Drug Master Files (DMF) submitted to the Center for Biologics Evaluation and Research (CBER). The draft guidance document describes the circumstances in which CBER will accept a Type V Drug Master File without a letter of intent from the DMF holder. The information in the DMF may be used to support an application or supplement, such as an investigational new drug application (IND), biologics license application (BLA), or a new drug application (NDA) submitted to CBER.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by November 21, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (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: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research '' dated August 2001. The draft guidance document discusses Type V DMFs submitted to CBER. The draft guidance document describes the circumstances in which CBER will accept a Type V DMF without a letter of intent to FDA from the DMF holder. A drug master file is a submission of information to FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drugs and biological products. The information in the DMF may be used to support an application or supplement, such as an IND, BLA, or an NDA.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The