of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of the meeting(s) shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: May 19, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–13821 Filed 5–23–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93S–0220]

Discontinuation of an Electronic Docket for Medical Device/Radiological Health Policy Statements and Operating Procedures Guide; Establishment of World Wide Web Site

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is discontinuing an electronic docket for policy speeches, policy statements, and standard operating procedure guides pertaining to product evaluation and regulatory enforcement for its medical device and radiological health programs. In its place, the agency has established a World Wide Web (WWW) site. The electronic docket, a computer bulletin board service which has been operating since 1993, served both as a repository for critical policy documents generated by the Center for Devices and Radiological Health (CDRH) and as a public display mechanism for access by representatives of the industry and other interested persons. That service ended October 1, 1996, and its contents transferred to a CDRH web site

on the WWW. FDA believes that the transfer will allow CDRH to expand both the amount of information available and the number of users that can access the information.

ADDRESSES: Submit written comments on the electronic docket to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 ext. 124, E-Mail: DSMO@FDAR.CDRH.FDA.GOV.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 27, 1993 (58 FR 40150), FDA announced, among other things, the establishment of a public docket for policy speeches, policy statements, and standard operating procedure guides pertaining to product evaluation and regulatory enforcement for its medical device and radiological health programs. This docket was intended to operate on a 1-year trial basis and serve as a repository for critical policy documents generated by the Center for Devices and Radiological Health (CDRH) and as a public display mechanism for access by representatives of the industry and other interested persons. The public docket contained ''hard copies'' of documents and was maintained through FDA's Dockets Management Branch. This action was intended to serve as an overall communications initiative to endure uniform and timely access to important information. The trial period for this public began July 27, 1993, and was intended to end July 27, 1994.

To further increase industry access to major CDRH documents in a real time and dynamic fashion, a nationwide electronic docket was established concurrently with the public (''hard copy'') docket and contained the same information as the public docket. The electronic docket allowed medical device companies, clinical researchers, manufacturers of radiation-emitting products, and others to electronically access the same documents available in the public docket. The documents could be read directly on the requestor's computer screen, printed at the requestor's terminal, downloaded to the requestor's personal computer, or be requested by mail. The system was menu-driven and included automated searching capabilities.

In the **Federal Register** of February 7, 1995 (60 FR 7204), FDA issued a notice that extended, for an indefinite period of time, this electronic docket. The agency also decided to stop maintaining a public ''hard copy'' docket. During its trial period, the success of the electronic docket as an information dissemination source was clearly demonstrated by the high volume of electronic accessions and transfers. However, demand soon outstripped the ability of the computer bulletin board service, which restricts the numbers of users that can simultaneously access the system. In order to increase the level of service to the public, the computer bulletin board service has been supplanted by the WWW. The technology offered by the WWW has enabled CDRH to logarithmically expand both the amount of information available and the number of users that can access the information. The CDRH web site Home Page is located at TTP://WWW.FDA.GOV/CDRH and is linked to FDA's Home Page. Through FDA's Home Page, the web site Home Pages of many other FDA components, such as Import Operations and Field Activities, can also be accessed.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the discontinuation of the electronic docket. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–13819 Filed 5–23–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Opportunity for a Cooperative Research and Development Agreement (CRADA) Partner To Develop a Diagnostic System for Identifying Infectious Agents

SUMMARY: The Department of Health and Human Services (DHHS), National Institute of Health Clinical Center (NIHCC) is seeking a Cooperative Research and Development Agreement (CRADA) partner to further develop a collaboration with NIHCC, a diagnostic system for identifying infectious agents.

Investigators at the National Institute of Health, Clinical Center (NIHCC) and University of Maryland have been developing a reliable and easy to use detection system for identifying various infectious agents. The detection system can identify, with high specificity, infectious agents by type and subtype (e.g. HIV, HCV and HIV–1 type A, HIV–2 type B respectively. This technology is based upon enzyme recognition and site-directed cleavage of a DNA oligo probe, whose sequence allows for hybridization with an RNA or DNA target strand. Further development is needed to improve sensitivity for diagnostic use via signal amplification methodologies.

ADDRESSES: For more information, please contact John Gill (Tel# 301–496–0477, Fax # 301–402–2117), Office of Technology Development, National Cancer Institute, 6120 Executive Plaza South, Ste. 450; Bethesda, MD 20892–7182. For hand carry or overnight delivery please substitute ''Rockville, MD 20852'' for ''Bethesda, MD 20892–7182'' in the above address.

DATES: In view of the important priority of developing the diagnostic systems, interested parties should notify this office in writing no later than July 28, 1997.

SUPPLEMENTARY INFORMATION: A Cooperative Research and Development Agreement of ''CRADA'' means the anticipated joint agreement to be entered into by NIHCC pursuant to the Federal Technology Transfer Act (''FTTA'') of 1986 and amendments (including 104 P.L. 113) to collaborate on the specific research project described below. As provided by the FTTA, the selected CRADA partner is granted an option to elect an exclusive or non-exclusive license to a field of use for subject invention(s) arising under and within the scope the CRADA research plan.

NIHCC Will—

Provide assay information, protocol(s) and/or method(s) for the detection and subtyping of various infectious agents;

Provide intellectual guidance and assistance for improving assay sensitivity by signal amplification;

Provide facilities and biological materials for evaluation and validation of the assay;

Provide information on nuclei acid sequence and expression of the enzyme;

Provide assistance with subcloning, over-expression and purification of the enzyme;

Provide personnel to support and facilitate completion of the studies.