scientific assessment and assigned score. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947–47951.

Application Submission and Deadlines

A. Preapplication Letter of Intent

Although not a prerequisite of application, a non-binding letter of intent-to-apply is requested from potential applicants. The letter should be submitted to the Grants Management Officer (whose address is reflected in section B, ''Applications''). It should be postmarked no later than June 28, 1996. The letter should identify the announcement number, name of principal investigator, and specify the priority area to be addressed by the proposed project. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

B. Applications

Applicants should use Form PHS–398 (OMB Number 0925–0001) and adhere to the ERRATA Instruction Sheet for Form PHS–398 contained in the Grant Application Kit. Please submit an original and five copies on or before July 26, 1996 to: Ron Van Duyne, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 321, MS-E13, Atlanta, GA 30305.

C. Deadlines

1. Applications shall be considered as meeting a deadline if they are either:

A. Received at the above address on or before the deadline date, or

B. Sent on or before the deadline date to the above address, and received in time for the review process. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be accepted as proof of timely mailings.

2. Applications which do not meet the criteria above are considered late applications and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332–4561. You will be asked your name, address, and phone number and will need to refer to Announcement 657. You will receive a complete program description, information on application procedures, and application forms. In addition, this announcement is also available through the CDC Home Page on the Internet. The address for the CDC Home Page is http://www.cdc.gov. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Georgia Jang, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., MS–E13, Atlanta, GA 30305, telephone (404) 842–6796; fax: 404–842–6513; internet: glj2@opspgo1.em.cdc.gov. Programmatic technical assistance may be obtained from Roy M. Fleming, Sc.D., Associate Director for Grants, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Building 1, Room 3053, MS–D30, Atlanta, GA 30333, telephone (404) 639–3343; fax: 404–639–4616; internet: rmf2@niood1.em.cdc.gov.

There may be delays in mail delivery as well as difficulty in reaching the CDC Atlanta offices during the 1996 Summer Olympics (July 19–August 4). Therefore, in order to receive more timely response to questions please use INTERNET/E-Mail, follow all instructions in this announcement and leave messages on the contact person's voice mail.

Please refer to announcement number 657 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: May 24, 1996.

Donald L. Holderman,

Acting Director, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–13676 Filed 5–30–96; 8:45 am]

BILLING CODE 4163–19–P

[Announcement 660]

Tuberculin Skin Testing Demonstration Projects; and Evaluation of Counseling and Testing of Tuberculosis Patients for Human Immunodeficiency Virus Infection and Reporting of Test Results

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for a cooperative agreement program for two projects: (1) Tuberculin Skin Testing (TST) Demonstration Projects; and (2) Evaluation of Counseling and Testing of Tuberculosis (TB) Patients for Human Immunodeficiency Virus (HIV) Infection and Reporting of Test Results.

CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2000,'' a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of HIV Infection and Immunization and Infectious Diseases. (To order a copy of ''Healthy People 2000,'' see the section ''WHERE TO OBTAIN ADDITIONAL INFORMATION.'')

Authority

This program is authorized under Section 317E of the Public Health Service Act [42 U.S.C. 247b-6], as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants are the official public health agencies of States and local governments or their bona fide agents. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments.

Availability of Funds

Tuberculin Skin Testing Demonstration Projects

Approximately $750,000 is available in FY 1996 to fund approximately 8–10 awards. It is expected that the average award will be $75,000, ranging from $50,000–$200,000. Funding estimates are subject to change. It is expected that awards will begin on or about September 1, 1996, and will be made for a 12-month budget period within a project period of up to 2 years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Evaluation of Counseling and Testing of TB Patients for HIV Infection and Reporting of Test Results

Approximately $750,000 per year is available in FY 1996 to fund approximately 4–6 awards. It is expected that the average award will be $125,000, ranging from $100,000–$200,000. Funding estimates are subject to change. It is expected that awards will begin on or about September 1, 1996, and will be made for a 12-month budget period within a project period of up to 2 years. Funding estimates may vary and are subject to change.

Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

Purpose

The purpose of the TST Demonstration Projects is: (1) Develop model TST programs in health departments and health care facilities; (2) track and monitor TST data and TB infections among health care workers; and (3) pilot a microcomputer software system developed by CDC to assist in the collection , tracking, management, and analysis of occupational TB exposures and infections.

The purpose of the Evaluation of Counseling and Testing of TB Patients for HIV Infection and Reporting of Test Results is: (1) To assess current HIV counseling and testing practices for TB patients; (2) to evaluate the extent to which TB patients are receiving counseling and testing; (3) to characterize TB patients who are not being tested and barriers to testing; (4) to evaluate the extent to which HIV results on TB patients known to be coinfected are reported to the State or local health department TB program; and (5) to characterize patients who were tested but are not being reported to the State or local health department TB program, and barriers to reporting HIV test results.

This project is intended to assist State and local TB control and AIDS programs to: (1) identify barriers to HIV counseling and testing of TB patients and to sharing data between TB and AIDS programs; and (2) develop guidelines and initiate programs that will overcome these barriers within the health department and the provider community.

Program Requirements

In conducting activities to achieve the purpose of the TST Demonstration Projects, the recipient shall be responsible for the activities listed under A. (Recipient Activities), and CDC will be responsible for the activities under B. (CDC Activities):

A. Recipient Activities

1. Conduct a program for health department personnel with direct patient contact or contract with a hospital to perform TST of hospital employees. In conducting the program the applicant will perform skin testing at one or more health department facilities or hospitals where health care workers (HCWs) are potentially exposed to TB.

Where employees have been exposed, the applicant will:

a. Perform contact investigations of HCWs exposed to an infectious TB patient who was not recognized and appropriately isolated.

b. Collect information on the circumstances surrounding these HCW exposures.

c. Initiate appropriate TST for exposed HCWs, including baseline and follow-up testing.

d. Clinically evaluate all employees with a TST conversion.

The applicant in performing the TST program for employees on a routine basis will be required to:

a. Use a two-step Mantoux test for all initial tests to minimize the likelihood of interpreting a boosted reaction as a true conversion due to recent infection.

b. Place and read a TB skin test on all HCWs. This will include measures or incentives likely to enhance workers' compliance with such testing.

c. Perform subsequent Mantoux testing annually (or more frequently if appropriate for the level of risk in the occupational group or facility) of all employees whose initial skin tests were negative.

d. Directly observe the reading of the TB skin test (in mm of induration) by personnel trained in correct placement and reading of Mantoux skin tests.

e. Confidentially assess potential pertinent demographic factors, (such as, gender, race/ethnicity, country of birth, and history of receipt of Bacille Calmette-Guerin) and occupational factors, (such as, occupation and worksite) which may place HCWs at risk for TB exposure.

2. Use CDC-developed software to assist in the collection, tracking, management, and analysis of data from TST programs.

3. Follow CDC guidelines for TST. A copy of the guidelines will be included in the application kit.

4. Implement a research protocol jointly developed with CDC for the TST demonstration project.

5. Use CDC-developed skin test software to enter all TST information onto the software and send a diskette of the database to CDC on a monthly basis.

6. Develop forms appropriate to their sites for the collection of data including HCW's demographics, occupational information, TST information, and results of follow-up clinical evaluations for persons with reactive skin tests.

7. Ensure that all data are kept confidential and in secured files.

B. CDC Activities

1. Jointly develop a research protocol for the TST demonstration project.

2. Provide technical assistance in implementation of the TST program.

3. Provide one or more versions of microcomputer software for use in the project.

4. Train health department personnel in the use of the software.

5. Develop a plan for data management and for data transfer to CDC.

6. Review site performance and ensure compliance with the study protocol.

7. Conduct data analysis and summarize and present findings.

In conducting activities to achieve the purpose of the Evaluation of Counseling and Testing of TB Patients for HIV Infection and Reporting of Test Results, the recipient shall be responsible for the activities listed under A. (Recipient Activities), and CDC will be responsible for the activities under B. (CDC Activities):

A. Recipient Activities

1. Provide a joint training session to personnel from TB and AIDS programs in local and State health departments. Training will include the latest CDC recommendations for TB prevention and control, the reasons for collaboration between the two groups, surveillance mechanisms and definitions, the importance of and methods for

maintaining confidentiality and availability of services for counseling, testing, and treating HIV-infected TB patients.

2. Assess current practices and policies of TB care providers who have reported cases to the health department in the past year, including policies and practices for HIV counseling and testing of TB patients, availability of services for coinfected patients, referral for services, reporting of coinfected patients, and perceived barriers to testing and reporting.

3. Implement a study protocol, developed jointly with CDC, to determine by medical record review whether TB patients, age 25–44 years, were offered HIV counseling and testing, the results of such testing, whether patients were questioned about HIV risk factors, missed opportunities for counseling and testing, and whether HIV-positive patients were referred for HIV-related services. If HIV status was known to the TB care provider, document the effect of this knowledge on TB care and on contact investigations. Other possible sources of documentation of HIV counseling and testing may include matching with the AIDS registry and the HIV reporting registry, HIV counseling and testing records, sexually transmitted disease registries and other public health records depending on availability and local confidentiality requirements. For patients whose HIV test results were already reported to the TB program, the medical record review will ascertain their mechanism through which the HIV results was reported and their subsequent HIV service referrals.

4. Evaluate the completeness of the TB surveillance system by matching the AIDS and TB registries.

5. Ensure that all data are kept confidential and in secured files.

6. Based on the results of above evaluations, describe barriers to providing HIV counseling and testing to TB patients and to reporting HIV results to the TB program. Make recommendations and initiate programs to overcome identified barriers and to improve coverage of HIV counseling and testing, reporting of HIV test results and provision of services (or referral for services) for coinfected patients.

7. Participate in two meetings to be held in Atlanta, GA, each one day in length, one each year of the project, with other study participants and staff from the Division of TB Elimination and the Division of HIV/AIDS Prevention, CDC.

B. CDC Activities

1. Provide assistance in developing a protocol for conducting the Recipient Activities described above.

2. Plan and organize the annual meetings for recipient representatives and staff from the Division of TB Elimination and the Division of HIV/AIDS Prevention, CDC .

3. Provide technical consultation as needed for training, implementing the protocol, and interpreting and using the results of the project.

4. Review site performance and ensure compliance with the study protocol.

5. Assist with data management.

Evaluation Criteria

Applications for the Tuberculin Skin Testing Demonstration Projects will be reviewed and evaluated according to the following criteria (100 points maximum):

A. The extent of the problem of TB, HIV, MDR TB, and TB/AIDS in the applicant's area. (10 Points)

B. The extent to which an efficient and effective TST program exists in the facility proposed for the project. This includes the compliance rate with the TST testing program. If compliance rates are sub-optimal, the extent to which the applicant's plan for improving compliance during the project period is likely to succeed. In addition, the degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. Specifically the following items will be addressed:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The appropriateness of the proposed justification when representation is limited or absent.

c. Whether the design of the study is adequate to measure differences when warranted.

d. Whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits is documented. (30 Points)

C. Agreement by the applicant to pilot test CDC-developed software and provide diskettes of the database to CDC on a monthly basis. The extent to which the applicant's data management plan demonstrates an ability to ensure the integrity of the data. (30 Points)

D. The extent to which the applicant describes how the study will be administered, including the size, qualifications, duties and responsibilities, and time allocation of the proposed staff, the availability of the facilities to be used, and a schedule for accomplishing the activities, including time frames. If a contract with a hospital is proposed, a letter of support must be included. (30 Points)

E. Other (Not Scored)

Budget

Consideration will be given to the extent to which the budget is reasonable, clearly justifiable, and consistent with the intended use of funds.

Human Subjects

Procedures adequate for the protection of human subjects must be documented: (1) Protections appear adequate and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate resulting in unacceptability of the entire application.

Applications for the Evaluation of Counseling and Testing of TB Patients for HIV Infection and Reporting of Test Results will be reviewed and evaluated according to the following criteria (100 points maximum):

A. Understanding the problem (10 points).

B. Plan for required activities. In addition, the degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. Specifically the following items will be addressed:

a. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

b. The appropriateness of the proposed justification when representation is limited or absent.

c. Whether the design of the study is adequate to measure differences when warranted.

d. Whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits is documented. (50 points)

C. Collaboration (10 points).

D. Experience in related activities (10 points).

E. Personnel and management plan (20 points).

F. Other (Not Scored).

Budget

Consideration will be given to the extent to which the budget is reasonable, clearly justifiable, and consistent with the intended use of funds.

Human Subjects

Procedures adequate for the protection of human subjects must be documented: (1) Protections appear adequate and there are no comments to make or concerns to raise, (2) protections appear adequate, but there are comments regarding the protocol, (3) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects, or (4) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate resulting in unacceptability of the entire application.

Funding Priority

Funding priority for the Tuberculin Skin Testing Demonstration Projects may be given to ensure geographic balance, urban and rural balance, high and low prevalence of HIV infection, and high and low TB morbidity areas.

Funding Priority for the Evaluation of Counseling and Testing of TB Patients for HIV Infection and Reporting of Test Results will be given to applicants that demonstrate a need to improve HIV counseling and testing of TB patients and reporting of test results. Funding priority also may be given to ensure a geographic balance, urban and rural high and low prevalence of HIV infection and high and low TB morbidity.

Interested persons are invited to comment on the proposed funding priority. All comments received on or before July 1, 1996, will be considered before final funding priority is established. If the funding priority should change as a result of any comments received, a revised announcement will be published in the Federal Register and revised applications will be accepted prior to the final selection of awards. Written comments should be addressed to: Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–15, Atlanta, GA 30305.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should send them to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–15, Atlanta, GA 30305, not later than 60 days after the application deadline date. The Program Announcement Number and Program Title should be referenced on the document. CDC does not guarantee to ''accommodate or explain'' State process recommendations it receives after that date. Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to CDC, they should forward them to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–15, Atlanta, GA 30305. This should be done no later than 60 days after the application deadline date. CDC does not guarantee to ''accommodate or explain '' for tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.947, TB Demonstration, Research, Public and Professional Education Projects.

Other Requirements

Paperwork Reduction Act: Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Confidentiality: Applicants must have in place systems to ensure the confidentiality of all patient records.

Human Subjects: The applicant must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurances must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and forms provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of the IHS will be involved or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Women, Racial and Ethnic Minorities: It is the policy of the CDC to ensure that women and racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaska Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947–47951 (a copy is included in the application kit).

Pre- and Post-test Counseling and Partner Notification: Recipients are required to provide HIV antibody testing to determine a person's HIV infection status; therefore, they must comply with State laws and regulations and CDC

guidelines regarding pre- and post-test counseling and partner notification of HIV-seropositive patients. A copy of the guidelines will be included in the application kit. Recipients must also comply with State and local health department requirements relating to specific reportable diseases or conditions. Recipients must provide referrals for HIV diagnosis and treatment.

HIV/AIDS Requirements: Recipients must comply with the document entitled ''Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions'' (June 1992), a copy of which is included in the application kit. In complying with the requirements for a program review panel, recipients are encouraged to use an existing program review panel such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a government health department consistent with the Content guidelines. The names of the review panel members must be listed on the Assurance of Compliance form (CDC 0.1113), which is included in the application kit.

Application Submission and Deadline

The original and two copies of the application must be submitted to: Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E–15, Atlanta, GA 30305, on or before July 29, 1996.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date, or

(b) Sent on or before the deadline date and received in time for submission to the objective review committee. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. *Late Applications:* Applications that do not meet the criteria in 1.(a) or 1.(b) are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

Business management technical assistance may be obtained from Juanita Dangerfield, Grants Management Specialist, at telephone (404) 842–6577, fax: (404) 842–6513, or INTERNET address: <jdd2@opspgo1.em.cdc.gov>.

Programmatic technical assistance may be obtained from Eugene McCray, M.D., Division of Tuberculosis Elimination, at telephone (404) 639–8117.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''INTRODUCTION'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Atlanta, Georgia, will be the host of the 1996 Summer Olympics Games (July 19 through August 4, 1996). As a result of this event, it is likely that the Procurement and Grants Office (PGO) may experience delays in the receipt of both regular and overnight mail deliveries. Contacting PGO employees during this time frame may also be hindered due to the possible telephone disruptions.

To the extent authorized, please consider the use of voice mail, e-mail, and facsimile transmissions to the maximum extent practicable. Please do not fax lengthy documents or grant applications.

This announcement will be available on one of two Internet sites on the publication date: CDC's home page at http://www.cdc.gov, or at the Government Printing Office home page (including free access to the Federal Register) at http://www.access.gpo.gov.

Dated: May 24, 1996.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–13675 Filed 5–30–96; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 96D–0148]

Medical Devices; Medical Device User Facility and Distributor Reporting; Guidance Documents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three guidance documents entitled ''Medical Device Reporting: An Overview,'' ''Medical Device Reporting for User Facilities,'' and ''Medical Device Reporting for Distributors.'' These guidance documents provide information to help facilitate compliance with the agency's Medical Device Reporting (MDR) requirements. The agency is also announcing the availability of the following final MDR reporting forms: FDA Form 3419, Semiannual User Facility Report; FDA Form 3417, Baseline Report; and FDA Form 3381, Annual Certification. Elsewhere in this issue of the Federal Register, FDA is publishing a notice of availability of, and requesting comments on, a draft guidance document focusing on reporting by manufacturers.

DATES: Written comments on the guidance documents may be submitted at any time.

ADDRESSES: Submit written comments on the three guidance documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments on the three guidance documents should be kept separate and identified by their respective titles. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance documents and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons interested in obtaining copies of the guidance documents and reporting forms may use the World Wide Web. FDA's home page address may be accessed at http://www.fda.gov and then select the Medical Devices and Radiological Health option. Next, select the program areas option and scroll down to Medical Device Reporting. The documents will be listed and available for downloading.

Anyone with a video terminal or personal computer with a modem can obtain these documents from the electronic docket administered by DSMA (1–800–252–1366 or 1–301–594–2741) by making the following menu choices: 5–Postmarket Surveillance; 2–Medical Device Reports—Policies/Guidelines.

Individuals unable to use the above two options may request information about obtaining paper copies of these documents through the CDRH Facts-on-Demand system by dialing 1–800–899–