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–

0381 or 1–301–827–0111. After following the voice prompts, request document number 799. FDA has arranged to have other government, industry, and health care organizations provide paper copies of these documents for a fee that each organization will set for itself.

FOR FURTHER INFORMATION CONTACT: Earl W. Robinson, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–2735.

SUPPLEMENTARY INFORMATION:

I. Background

On November 26, 1991 (56 FR 60024), under the Safe Medical Devices Act of 1990 (Pub. L. 101–629), FDA issued a tentative final rule proposing to implement regulations requiring user facility and distributor adverse event reporting (hereinafter referred to as the November 1991 tentative final rule). In the November 1991 tentative final rule, FDA also proposed to amend the existing manufacturer reporting regulations to conform to the proposed user facility and distributor reporting requirements.

Subsequent to FDA's issuance of the November 1991 tentative final rule, the Medical Device Amendments of 1992 (Pub. L. 102–300) were enacted on June 16, 1992, and amended certain provisions of section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) relating to reporting of adverse device events.

On December 11, 1995 (60 FR 63578), the agency published the MDR regulation for user facilities and manufacturers, based on comments to the November 1991 tentative final rule. The requirements for manufacturer and user facility reporting are found in part 803 (21 CFR part 803). The reporting requirements for distributors fell under a different implementation timetable. On May 28, 1992, the provisions of the November 1991 tentative final rule pertaining to distributor reporting became final by operation of law. Accordingly, medical device distributors are currently subject to the reporting regulations contained in the November 1991 tentative final rule and codified in part 804 (21 CFR part 804). FDA intends to issue a proposed rule to make the distributor reporting requirements consistent with the manufacturer and user facility reporting requirements.

A. Guidance for User Facilities and Distributors

Due to the diversity and complexity of medical device products, no regulation could address each possible reporting scenario. Therefore, the agency is providing three guidance documents entitled ''Medical Device Reporting: An Overview,'' ''Medical Device Reporting for User Facilities,'' and ''Medical Device Reporting for Distributors.'' These guidance documents contain information describing who is covered by the MDR rule, who is responsible for reporting, how to report, and when to report. The documents also contain statements of FDA's policy, interpretations of the regulation, and answers to frequently asked questions. 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.

B. MDR Reporting Forms

The MDR final rule requires that MDR reports be submitted using the appropriate form, or an approved electronic equivalent. The actual forms were made available for public comment, were approved by the Office of Management and Budget (OMB) through February 28, 1999, under OMB control number 0910–0059, and were announced as final in the Federal Register of April 11, 1996 (61 FR 16043). The April 11, 1996, final rule also extended the effective date of the MDR final rule for manufacturers and user facilities to July 31, 1996, in order to provide additional time for compliance. This notice announces the availability of the following MDR forms: FDA Form 3419, Semiannual User Facility Report; FDA Form 3417, Baseline Report; and FDA Form 3381, Annual Certification. FDA Form 3500A, the MEDWATCH Form, has been in use for several years and is available from the same sources listed above. This form, or an approved electronic equivalent, will continue to be used for reporting individual adverse events. Although manufacturers, distributors, and device user facilities may immediately begin using the forms announced in this notice to submit reports required under the MDR regulations, use of the forms will not be required until July 31, 1996, the effective date of the MDR final rule.

II. Significance of a Guidance

A guidance document does not bind FDA or the public, and does not create or confer any rights, privileges, or benefits for or on any person; however, it does represent the agency's current thinking on the subjects discussed therein.

III. Request for Comments

All guidance documents developed by FDA are open to public comment. Therefore, interested persons may submit comments regarding the final guidance documents that are being announced in this notice. Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the three guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified by the title of the respective guidance document and with the docket number found in brackets in the heading of this document. Copies of the three guidance documents and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in reviewing and revising the guidance documents.

Dated: May 21, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–13666 Filed 5–30–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0137]

Medical Device Reporting, Draft Guidance Document for Manufacturers; Notice of Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Medical Device Reporting for Manufacturers.'' This guidance contains information to help facilitate manufacturer compliance with the new Medical Device Reporting (MDR) regulation. FDA is inviting comments on the draft guidance, particularly on matters not already addressed in the draft manufacturer device reporting guidance.

DATES: Submit written comments by August 29, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified by title and the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments are