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

available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Persons interested in obtaining a copy of the draft guidance document may do so by using 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 then select Medical Device Reporting. All Relevant documents will be listed and available for downloading.

Anyone with a video terminal or personal computer with a modem can obtain the draft guidance document from the electronic docket administered by the Division of Small Manufacturers Assistance (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, through the CDRH Facts-on-Demand system, about obtaining paper copies of the document, 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 the document 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

Under the Safe Medical Devices Act of 1990 (Pub. L. 101–629) (SMDA), on November 26, 1991 (56 FR 60024), 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 this 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.

After FDA's issuance of the November 1991 tentative final rule, the Medical Device Amendments of 1992 (Pub. L. 102–300) (the 1992 amendments) 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), FDA published the MDR regulation for user facilities and manufacturers, based on comments to the November 1991 tentative final rule. In the Federal Register of April 11, 1996 (61 FR 16043), the effective date of this final rule was extended to July 31, 1996, in order to provide additional time for compliance. The requirements for manufacturer and user facility reporting are found at 21 CFR part 803.

II. Draft Guidance for Manufacturers

Due to the diversity and complexity of medical device products, no regulation could address each possible reporting scenario. Therefore, the agency is providing additional guidance to the industry. The agency has developed a draft guidance document entitled ''Medical Device Reporting for Manufacturers.'' This draft guidance contains information describing: Who is covered by the MDR rule, who is responsible for reporting, how to report, and when to report. The draft guidance also contains statements of FDA policy, interpretations of the regulation, and answers to frequently asked questions. The agency also addresses in this guidance, many questions which have been raised after to the publication of the November 1991 tentative final rule. However, because the agency anticipates that additional new questions and issues may be raised as the effective date of the MDR regulation approaches, the agency is issuing the manufacturer guidance as a draft document and specifically invites questions and comments on matters not already addressed in the draft guidance. The agency will consider all submitted comments when revising the draft guidance. The agency anticipates that a revised guidance document for manufacturers will be available by November 27, 1996. In the interim, FDA believes the information contained in the draft guidance will be useful to medical device manufacturers as they seek to implement the requirements of the new MDR final rule.

III. 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. The draft guidance document announced in this notice represents the agency's tentative thinking on issues related to manufacturer reporting.

IV. Request for Comments

Interested persons may, on or before August 29, 1996, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance entitled ''Medical Device Reporting for Manufacturers.'' 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 guidance and the docket number found in brackets in the heading of this document. Copies of the 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 revising the draft guidance document.

Dated: May 21, 1996.

Joseph A. Levitt,

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

[FR Doc. 96–13665 Filed 5–30–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings of the National Institute of Mental Health Special Emphasis Panel:

Agenda/Purpose: To review and evaluate grant applications.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: June 12, 1996.

Time: 6 p.m.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Michael D. Hirsch, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301, 443–1000.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: June 14, 1996.

Time: 12 p.m.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Michael D. Hirsch, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301, 443–1000.

Committee Name: National Institute of Mental Health Special Emphasis Panel.

Date: June 20, 1996.

Time: 8;30 a.m.

Place: The Latham Hotel Georgetown, 3000 M Street, NW., Washington, DC 2007.

Contact Person: Phyllis D. Artis, Parklawn Building, Room 9C–26, 5600 Fishers Lane,