FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING

USER Facility Reporting

Issue No. 5 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Summer 1993

DEVICE TRACKING FOR 26 DEVICES IS REQUIRED ON AUGUST 29, 1993

by Kathleen Shanahan and Ronald Ross

August 29, 1993, the effective date of the device tracking requirements, is almost here. In response to questions about device tracking received by the Food and Drug Administration (FDA), we are providing some background information and a discussion of what is required for tracked devices.

The purpose of device tracking is to assure that manufacturers of tracked devices (i.e., a device subject to tracking under section 519(e) of the Federal Food, Drug, and Cosmetic Act) can locate and recall defective or dangerous devices and notify patients using them. FDA has currently identified 26 devices that it considers subject to tracking. The Agency may add or remove devices from its illustrative listing of tracked devices as a result of its review of premarket applications, recall data, medical device reporting, inspections, petitions, or other information coming to its attention.

Readers of this publication will probably be most affected by the device tracking requirements for final distributors. A **final distributor** is any person who distributes to the patient a tracked device intended to be used by one patient for the life of the device. Examples of a final distributor are hospitals, licensed practitioners, retail pharmacies, and other types of device user facilities. Upon purchasing a tracked device, a final distributor must provide the manufacturer with the following information: (continued on page 2)

FDA Announces New MedWatch Program

by Cathy Hix

On June 3 the Food and Drug Administration (FDA) announced its new Medical Products Reporting Program, called "MedWatch" (June 3, 1993, Federal Register, pp. 31596-31614). The purpose of MedWatch is to simplify and consolidate the reporting of adverse events and product problems and to improve the consistency of the postmarket product information in the agency's databases.

The new MedWatch reporting form is available in two versions—one for voluntary and one for mandatory reporting. The new form is to be used for reporting serious adverse events and product problems not only with medical devices but also with human drugs, biologics (except vaccines), and special nutritional products. An adverse event is considered serious if the patient outcome involved death, a life-threatening condition, initial or prolonged hospitalization, disability, congenital anomaly, or required surgical or medical intervention to prevent permanent impairment or damage. (continued on page 3)

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Device Tracking ... (continued from page 1)

- the lot, batch or serial number, or other identifier used to identify the device;
- the date the device was received;
- the person from whom it was received; and
- if and when applicable, the date the device was explanted, the date of the patient's death, or the date the device was returned to the distributor, permanently retired from use, or permanently disposed.

When a final distributor sells or distributes a tracked device to a patient, it must provide the manufacturer with specific information to identify the device, the patient receiving the device, and the physician(s) who prescribed the device and is (are) following the patient, as well as other related information.

There may be circumstances when a user facility would be considered a multiple distributor under the device tracking regulations. A **multiple distributor** is a user facility, rental company, or any other entity that distributes to the patient a life-supporting, life-sustaining, or designated tracked device for use outside a user facility by more than one patient over the useful life of the device.

Multiple distributors must keep current records that include specific information to identify and locate each patient receiving a device from them. They must report this information within 5 working days of a manufacturer's request or within 10 working days of a request from FDA.

The Center for Devices and Radiological Health (CDRH) is developing a question and answer (Q&A) document to provide additional guidance on the device tracking regulations. We expect to distribute the Tracking Q&A document soon. To obtain a copy write to:

Division of Small Manufacturers Assistance (HFZ-220)
Office of Training and Assistance
FDA/CDRH
5600 Fishers Lane
Rockville, MD 20857

FAX 301-443-8818. ❖

Kathleen Shanahan, a Consumer Safety Officer in the Office of Compliance, and Ronald Ross, a Consumer Safety Officer in the Office of Standards and Regulations, are the Center's tracking experts and participated in writing the tracking regulation.

DEVICES TO BE TRACKED AS OF AUGUST 29, 1993

Vascular graft prosthesis of less than 6 mm diameter
Vascular graft prosthesis of 6 mm and greater diameter
Total temporomandibular joint prosthesis
Glenoid fossa prosthesis
Mandibular condyle prosthesis
Interarticular disc prosthesis (interpositional implant)
Ventricular bypass (assist) device
Implantable pacemaker pulse generator
Cardiovascular permanent pacemaker electrode
Annuloplasty ring
Replacement heart valve
Automatic implantable cardioverter/defibrillator
Tracheal prosthesis
Implanted cerebellar stimulator
Implanted diaphragmatic/phrenic nerve stimulator
Implantable infusion pump
Breathing frequency monitor (apnea monitor) including ventilatory efforts monitor
Continuous ventilator
DC-defibrillator and paddles
Silicone inflatable breast prosthesis
Silicone gel-filled breast prosthesis
Silicone gel-filled testicular prosthesis
Silicone gel-filled chin prosthesis
Silicone gel-filled Angelchik reflux valve
Infusion pump

MEDWATCH ... (continued from page 1)

Form 3500 is to be used by health professionals for **voluntary** reporting of adverse events or product problems to manufacturers or to FDA. It is a yellow, one-page, postage-paid document. The Agency also encourages health professionals to report problems with product quality such as defective devices, inaccurate or unreadable product labeling, packaging or product mix-up, contamination or stability problems, and particulate matter in injectable products.

When reporting on medical devices, user facilities should only use the voluntary version (Form 3500) for reporting those adverse events and product problems which are not required by law, i.e., device-related events where there is no patient death or serious injury involved.

Voluntary reporting by health professionals does not satisfy the facility's medical device reporting (MDR) requirements under the Safe Medical Devices Act (SMDA). Under SMDA, health professionals should follow the internal incident reporting procedures of their facilities.

Form 3500A, the **mandatory** reporting version, must be used by user facilities, distributors, and manufacturers to report under MDR when the final regulation is effective later this year. In the interim, user facilities are encouraged to use Form 3500A; however, all reporting requirements under SMDA and the 1984 MDR regulation, whichever is applicable, must be met.

The new MedWatch form will replace the following forms:

- FDA Form 2519f (Medical Device and Laboratory Product Problem Reporting Program)
- FDA Test Form 3375 (User Facility Report)
- FDA Form 3322 (Medical Device Report Form for Manufacturers)

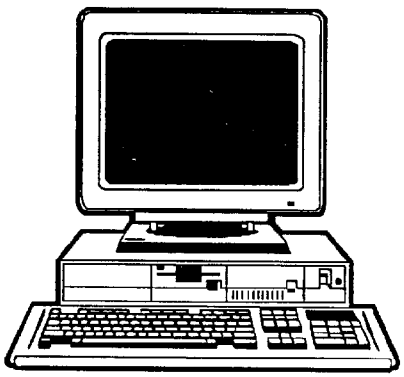
See page 4 for information about reporting electronically and obtaining copies of the MedWatch form.

We will update you on MedWatch in future Bulletin articles. ❖

Cathy Hix is a Management Analyst in the immediate Office of the Director, Office of Information Systems, CDRH.

MAUDE UPDATE

by Cathy Hix



The recent introduction of MedWatch has had a great impact on MAUDE. The staff of the Office of Information Systems has been busy modifying MAUDE to accept the new MedWatch forms. Actually, "modify" is an understatement. The changes to the MAUDE database have been massive. Essentially, all of the database software, including revision of the data entry screens and edits, had to be rewritten to accommodate the new information to be collected under MedWatch. We also had to convert all of the data previously collected to the new format.

Changes to MAUDE have included one very important revision: the database will now automatically link all of the reports from the various reporters (i.e., manufacturers, user facilities, distributors, and health professionals). The voluntary reports of an event will be linked to the mandatory reports of the same event, submitted under the Safe Medical Devices Act (SMDA) and medical device reporting (MDR). This change will result in a more complete postmarket database and a more accurate picture of overall device performance. The new MedWatch Form 3500 will be used by health professionals for voluntary reports. User facilities, distributors, and manufacturers will use Form 3500A for mandatory reporting. This is a change, particularly for health professionals who previously had reported under the voluntary Product Reporting Program (PRP). **MedWatch (Form 3500) replaces PRP.** (continued on page 4)

OBTAINING MEDWATCH FORMS AND INSTRUCTIONS

Form 3500 (Voluntary Reporting)

To assist health professionals with voluntary reporting using Form 3500, FDA has developed a guide entitled the "FDA Desk Guide to Reporting Adverse Events and Product Problems." The Desk Guide includes several copies of Form 3500 and step-by-step instructions for completing the form as well as sample reports, case studies and information on such issues as confidentiality. To obtain a copy of the Desk Guide, call 1-800-FDA-1088. Bulk copies of Form 3500 may be obtained from:

Consolidated Forms and Publications Distribution Center
Washington Commerce Center
3222 Hubbard Road
Landover, MD 20785

Form 3500A (Mandatory Reporting)

To receive up to 10 copies of Form 3500A, along with instructions and codes for completing the form, call the Division of Small Manufacturers Assistance at 1-800-638-2041 or write to:

Division of Small Manufacturers Assistance (HFZ-220)
Office of Training and Assistance
FDA/CDRH
5600 Fishers Lane
Rockville, MD 20857

Electronic Reporting

CDRH is planning a pilot program for electronic reporting of adverse events, and in preparation has made the "Draft Electronic Data Interchange (EDI) Standard" available electronically. Anyone can obtain a copy of the draft standard through Internet, using an "AutoReply" account that has been setup for this purpose. To do so, address a message to: **EDISTD01@FDADR.CDRH.FDA.GOV** and a copy of the draft will be delivered automatically to the requester's electronic mail address.

The Center is forming a working group, representing medical device users, manufacturers, and the telecommunications and EDI communities, to develop a final standard. The duration of the effort is not known. Most of the work will be performed by volunteers, and collaboration will be conducted electronically. Even after development of a final standard, software must still be developed and/or bought and tested. To participate in the working group, send a FAX to Isaac Hantman at 301-594-2968, including your name, phone number, and electronic address. Comments on the draft EDI standard should also be FAX'ed to Mr. Hantman at the above FAX number.❖

MAUDE UPDATE ... (continued from page 3)

User facilities and distributors, which are using the Test Form 3375 (the "interim form") to report under the requirements of SMDA, may continue to report with it or begin using the new form. Form 3500A will be required for mandatory reports when the final MDR regulation is published later this year.

While some changes to MAUDE are still in progress, the data entry programs and report-generation capabilities are operational for information submitted by health professionals, user facilities, and distributors. We are working to develop and implement the manufacturer reporting portions of the system, as well as additional review and analysis functions. We hope to have them operational when the final MDR regulation is published.❖

Cathy Hix is a Management Analyst in the immediate Office of the Director, Office of Information Systems, CDRH.

User Facility Reporting
A Quarterly Bulletin

The *User Facility Reporting Bulletin* is an FDA publication to assist hospitals, nursing homes, and other medical device user facilities in complying with their statutory reporting requirements under the Safe Medical Devices Act. The publication's contents may be freely reproduced. Comments should be sent to the Editor.

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Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

SEMIANNUAL REPORTS WERE DUE BY JULY 31

If any of your facilities filed with FDA and/or a manufacturer any reports of death, serious illness, or serious injury between January 1, 1993 and June 30, 1993, you are required to submit a semiannual report to FDA by July 31, 1993. Do not send a semiannual report if you have not reported any adverse events to manufacturers or to FDA during the previous six months.

The summary should include the following information excerpted from the November 26, 1991, **Federal Register** (submitting this information will take the place of completing FDA Form 222 which is not yet available).

1. User facility identification number;
2. Reporting year and period, e.g., January through June or July through December, 1993;
3. Facility name and complete address;
4. Total number of reports attached or summarized;
5. Lowest and highest report number of MDR reportable events for the semiannual reporting period, e.g., 0001-0014;
6. Name and complete address of the individual designated as the facility contact responsible for reporting device problems to FDA. Include a statement if the facility contact has changed since the last semiannual reporting period; and
7. Information for each MDR reportable event that occurred during the semiannual reporting period including:
   - the MDR report number;
   - the name of the manufacturer;
   - the brand and common name of the device;
   - the product model, catalog, serial, and lot number; and
   - a brief description of the event reported to the manufacturer.

In lieu of submitting the information in number 7 above, you can send a copy of each report submitted during the previous six months. Most user facilities find this option easier to fulfill. Copies can also facilitate the FDA audits, because the likelihood of transposition of numbers and other information is reduced.

Please write "Semiannual report" in the lower left corner of the envelope and send the report to:

Food and Drug Administration
Center for Devices and Radiological Health
MDR User Reporting
P.O. Box 3002
Rockville, MD 20847-3002

Questions about filing your semiannual report should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting Inquiries
1390 Piccard Drive
Rockville, MD 20850

FAX (301) 881-6670

QUESTIONS & ANSWERS

by Susan E. Bounds and Kathleen S. Shanahan

The following questions concern medical device tracking and user facility reporting. From the questions received, there appears to be some confusion about the two requirements. User facility reporting requires filing a medical device report (MDR) form for all incidents of device-related deaths, serious injuries, and serious illnesses for **all devices**. Device tracking requires the manufacturers of **26 types of devices** to maintain information about the location of the devices during distribution. If necessary, this information can be used to locate and recall defective or dangerous devices and to notify the patients using them. (See page 1 for articles on user facility reporting and device tracking.)

Q Is a hospital responsible for tracking the 21 devices listed in the winter issue of the User Facility Reporting Bulletin?

A Yes, a hospital is responsible for tracking if it sells or distributes to patients any of the 26 tracked devices. (Five devices have been added to the list since it was published in the May 29, 1992, **Federal Register**).

A hospital is considered to be a final distributor when it sells or distributes to the patient a "permanently implantable" or "designated" tracked device for implantation in, or use by, one patient over the useful life of the device. A hospital is considered to be a **multiple distributor** when it sells or distributes to patients a life-supporting, life-sustaining, or designated tracked device for use outside the hospital by more than one patient over the useful life of the device.

Q When will tracking be required?

A The tracking requirements become effective on August 29, 1993.

Q Is there a standard reporting form that I can use instead of one for drugs, one for vaccines, and now one for medical devices?

A Yes. FDA published a new MedWatch form for reporting in the June 3, 1993, **Federal Register**. The two versions (Form 3500 and Form 3500A) are "universal" and can be used by health professionals, user facilities, manufacturers, importers, and distributors to report adverse events related to products (except vaccines) regulated by FDA.

MedWatch is intended to simplify and improve reporting of serious adverse events to FDA and manufacturers. MedWatch Form 3500A may now be used for reporting and will be mandatory after the medical device reporting (MDR) regulation becomes effective later this year.

Q As an outpatient rehabilitation facility serving the physically disabled, we utilize none of the listed devices in our treatments, although we do see patients who have had some of the devices implanted elsewhere. Is a vocational evaluation, training, and job placement institution such as ours required to report? (The editor received this question in a letter from a rehabilitation facility.)

A This question commingles the requirements of MDR and tracking, which are not the same.

An outpatient rehabilitation facility is considered to be an **outpatient treatment facility** for the purposes of reporting adverse events related to medical device use. Any product used in the rehabilitation of a patient is probably a medical device and subject to mandatory reporting.

The tracking requirements apply to persons engaged in the manufacture and distribution of devices subject to tracking. An outpatient rehabilitation facility that does not sell or distribute any of the tracked devices to its patients is not required to comply with the tracking regulations.

Q I am hired by an agency to provide care for patients after they come home from the hospital. Many of them have an i.v. drip or an infusion pump. Do I need to report problems? Is my employer required to report? How are tracked devices different, since infusion pumps are on your list? (This question was asked in a telephone call to the editor.) (Continued on page 7)

QUESTIONS & ANSWERS ... (continued from page 6)

A If your employer is not part of a user facility (i.e., a hospital, nursing home, or outpatient treatment or diagnostic facility), there is no requirement at this time to report adverse events related to medical device use. Adverse events encountered by the professional staff may be voluntarily reported to the device manufacturer and/or to FDA.

FDA has designated by regulation a nonimplantable infusion pump as a "tracked device." Any distributor that provides this device to a patient for use outside a user facility is required to keep records of the device's location and to report this information to the manufacturer in accordance with the tracking regulation. Since you do not function as a manufacturer, final distributor, or multiple distributor, you have no responsibilities under the tracking regulation.

Q Do user facilities have to report problems since there is no final regulation (the subject of many telephone calls)?

A Absolutely! The requirement for user facilities to report patient deaths, serious illnesses, and serious injuries **became law** on November 28, 1991. The proposed regulation, which was published in the November 26, 1991, **Federal Register**, can be used as guidance until a final MDR regulation is published later this year.

Q What should I do with all of the adverse-event data that I have been sending to manufacturers for the last couple of years? (This question was asked in a letter to the editor.)

A Retain the files for two years from the reported date of each event. Clearly label the files as medical device reports (MDR) for easy retrieval and review by FDA personnel. In 1993 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) added compliance with the Safe Medical Devices Act reporting requirements as a condition of accreditation. When the MDR regulation becomes final later this year, separate MDR files will be required. This requirement, however, is not retroactive.

The individual files will be needed to write the January and July semiannual reports. **Do not file a semiannual report if you have not reported device adverse events to manufacturers or the FDA during the previous six months.** (See page 5 for a description of the information required in a semiannual report.)

Q I would like to know why orthopedic devices, probably more widely used than any other device except breast implants, are not included in the list of devices to be tracked which appeared in the May 29, 1992, Federal Register. (This is an excerpt from a letter received by the editor.)

A The widespread use of a device is not one of the statutory criteria requiring a device be tracked. Under section 519(e)(1) of SMDA, tracking is required for devices whose failure would be reasonably likely to have serious adverse health consequences and which are either permanent implants or life-sustaining or life-supporting devices used outside user facilities. The regulation defines a serious adverse health consequence as any significant adverse experience related to a device including device-related events that are life threatening or involve permanent or long-term injury or illness.

FDA is not aware of any permanently implanted orthopedic device whose failure can not be detected and a medical remedy sought in a timely manner to minimize the risk of serious adverse health consequences.

Widespread failure of a device is another factor that FDA may consider in determining whether or not a device should be designated as requiring tracking under section 519(e)(2). Presently, FDA is unaware of any orthopedic device that meets this criteria. If you are aware of failures, please report them, keeping the MDR requirements in mind.

Q Are ambulance services required to submit MDR reports under SMDA?

A An ambulance service is required to report if it is owned by a user facility, e.g., a hospital. Independent ambulance services are not considered to be user facilities; however, they may use the MedWatch voluntary report Form 3500 to report serious adverse events. ❖

Susan E. Bounds, a Consumer Safety Officer in the Office of Surveillance and Biometrics, CDRH, is a specialist in user facility reporting. Kathleen S. Shanahan, a Consumer Safety Officer in the Office of Compliance, CDRH, is a specialist in device tracking.