FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE REPORTING USER Facility Reporting

Issue No. 15 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Spring 1996

FDA EXTENDS EFFECTIVE DATE FOR MDR TO JULY 31

In the April 11, 1996, *Federal Register,* the Food and Drug Administration (FDA) announced that the Office of Management and Budget (OMB) had approved data collection for medical device reporting (MDR). (When the MDR final rule was published in the December 11, 1995, *Federal Register,* OMB had not yet approved data collection.) FDA also announced that the effective date of the MDR final rule was extended to July 31, 1996, to allow sufficient time to implement procedures for complying with the MDR final rule.

Effective July 31, 1996, user facilities must use **FDA Form 3500A** (the Mandatory MedWatch Form) to submit reports of individual adverse events and **FDA Form 3419** for semiannual reports if required. No semiannual report is required if a user facility did not submit any MDR reports during the reporting period. Also, manufacturers will be required to use Form 3500A and to submit annual MDR certification reports (FDA Form 3381) and MDR baseline reports (FDA Form 3417).

The two forms needed by user facilities are provided at the end of this bulletin. The forms, instructions, and coding manual necessary to complete FDA Form 3500A are available on the Internet at **http://www.fda.gov** and will be available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, in June 1996. Detailed instructions for using Internet appeared in the Winter 1995 Bulletin (Issue No. 14).✔

LIVE SATELLITE TELECONFERENCE ON MDR FINAL RULE

On May 7, 1996, from 1:00 - 4:00 p.m. eastern time, the Food and Drug Administration will present a live satellite teleconference to explain the new requirements of the Medical Device Reporting (MDR) final rule. The following topics will be presented:

- Purpose of MDR final rule and how it will affect your facility
- How to report adverse events and what forms to use
- Information required in MDR reports and how FDA uses it
- Semiannual reporting requirements
- Regulatory sanctions for non-compliance

There is no charge by FDA to receive this broadcast, but you must have access to a downlink station. Fees for downlink service vary; sometimes there is no fee. Contact local colleges, universities, state and municipal health offices, hotels, hospitals, and fire/rescue stations for help in locating a satellite dish. To obtain the satellite coordinates, you must call (800) 305-0748 to register and give your FAX number. FDA will FAX to you the satellite coordinates and important phone numbers to call during the broadcast.✔

In This Issue:

FDA MEDICAL DEVICE REPORTING WORKSHOPS

The Center for Devices and Radiological Health (CDRH) is pleased to announce medical device reporting (MDR) workshops to address issues related to user facility reporting requirements. The workshop sessions for user facilities will focus on basic reporting requirements, completion of reporting forms, and other compliance issues. They will be presented by CDRH's Office of Surveillance and Biometrics (OSB) and Division of Small Manufacturers Assistance (DSMA). Planned workshops are:

July 11, 1996 • Chicago, Illinois
8:30 a.m. - 5:00 p.m.
Nordic Hills Resort & Conference Center
250 W. Schick Road
Bloomingdale, IL 60108
(708) 529-0200

User facility reporting will be covered in the morning and manufacturer reporting in the afternoon. The $50 fee includes coffee breaks and lunch. Preregistration is recommended, since seating is limited. Make check or money order payable to North Central AFDO and send to Elizabeth Watkins, Illinois Department of Public Health, 525 W. Jefferson, Springfield, IL 62761; telephone (217) 785-2439.

July 17, 1996 • Minneapolis, Minnesota
Tenth Annual Biomedical Focus Conference & Exposition
Sponsored by The American Society for Quality Control (ASQC)
Minneapolis Convention Center
Minneapolis, MN 55403

Preregistration will be required, but the fee has not been set. For information, contact Best Meetings, Inc., at (612) 858-8875.

Early September 1996 • San Antonio, Texas

Details will be available after July 1 from CDRH's Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041.

NOTE: Local user facilities have been notified of these MDR workshops:
•**May 2** - Long Island, New York, Melville Marriott •**May 21** - Tampa, Florida, Hyatt Regency Tampa
•**June 6** - New York City, Jacob K. Javits Convention Center.

For additional information, contact OSB's Reporting Systems Monitoring Branch at (301) 594-2735 and mention the MDR workshops. You may also FAX your questions to (301) 827-0038.✔

Form Approved: OMB No. 0910-0281 Expires: 1/31/96
See OMB statement on reverse

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page ___ of ___

Mfr report #
UF/Dist report #
FDA Use Only

PLEASE TYPE OR USE BLACK INK

A. Patient information

1. Patient Identifier
In confidence

2. Age at time of event:
or
Date of birth:

3. Sex
☐ female
☐ male

4. Weight
___ lbs
or
___ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
☐ death ___ (mo/day/yr)
☐ life-threatening
☐ hospitalization – initial or prolonged
☐ disability
☐ congenital anomaly
☐ required intervention to prevent permanent impairment/damage
☐ other: ___

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1
#2

2. Dose, frequency & route used
#1
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1
#2

4. Diagnosis for use (indication)
#1
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # – for product problems only (if known)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
☐ health professional
☐ lay user/patient
☐ other: ___

5. Expiration date (mo/day/yr)

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter

1. Name & address

phone #

2. Health professional?
☐ yes ☐ no

3. Occupation

4 Initial reporter also sent report to FDA
☐ yes ☐ no ☐ unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

FDA Form 3500A (6/93)

Medication and Device Experience Report
(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

Page ____ of ____

FDA Use Only

F. For use by user facility/distributor–devices only

1. Check one ☐ user facility ☐ distributor
2. UF/Dist report number
3. User facility or distributor name/address
4. Contact person
5. Phone Number
6. Date user facility or distributor became aware of event (mo/day/yr)
7. Type of report ☐ initial ☐ follow-up # ____
8. Date of this report (mo/day/yr)
9. Approximate age of device
10. Event problem codes (refer to coding manual) patient code ____ - ____ - ____ device code ____ - ____ - ____
11. Report sent to FDA? ☐ yes ____ (mo/day/yr) ☐ no
12. Location where event occurred ☐ hospital ☐ home ☐ nursing home ☐ outpatient treatment facility ☐ outpatient diagnostic facility ☐ ambulatory surgical facility ☐ other: ____ specify
13. Report sent to manufacturer? ☐ yes ____ (mo/day/yr) ☐ no
14. Manufacturer name/address

G. All manufacturers

1. Contact office – name/address (& mfring site for devices)
2. Phone number
3. Report source (check all that apply) ☐ foreign ☐ study ☐ literature ☐ consumer ☐ health professional ☐ user facility ☐ company representative ☐ distributor ☐ other: ____
4. Date received by manufacturer (mo/day/yr)
5. (A) NDA # ____ IND # ____ PLA # ____ pre-1938 ☐ yes OTC product ☐ yes
6. If IND, protocol #
7. Type of report (check all that apply) ☐ 5-day ☐ 15-day ☐ 10-day ☐ periodic ☐ initial ☐ follow-up # ____
8. Adverse event term(s)
9. Mfr. report number

H. Device manufacturers only

1. Type of reportable event ☐ death ☐ serious injury ☐ malfunction (see guidelines) ☐ other: ____
2. If follow-up, what type? ☐ correction ☐ additional information ☐ response to FDA request ☐ device evaluation
3. Device evaluated by mfr? ☐ not returned to mfr. ☐ yes ☐ evaluation summary attached ☐ no (attach page to explain why not) or provide code: ____
4. Device manufacture date (mo/yr)
5. Labeled for single use? ☐ yes ☐ no
6. Evaluation codes (refer to coding manual) method ____ - ____ - ____ - ____ results ____ - ____ - ____ - ____ conclusions ____ - ____ - ____ - ____
7. If remedial action initiated, check type ☐ recall ☐ repair ☐ replace ☐ relabeling ☐ other: ____ ☐ notification ☐ inspection ☐ patient monitoring ☐ modification/ adjustment
8. Usage of device ☐ initial use of device ☐ reuse ☐ unknown
9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:
10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

CDRH Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

MEDICAL DEVICE REPORTING
SEMIANNUAL USER FACILITY REPORT

OMB: 0910-0059
Exp. Date: 02/28/99

PART 1 - COVER SHEET

If MDR reports were not submitted to either the FDA or a device manufacturer during this reporting period, DO NOT submit a semiannual report.

PART 1 INSTRUCTIONS

Complete one copy of the following information as a cover page for the semiannual report and return to the address listed above. This report should NOT include reports that are not required but have been submitted voluntarily.

1. REPORT PERIOD

☐ JAN - JUN ____ (Y Y Y Y)

☐ JUL - DEC ____ (Y Y Y Y)

2. USER FACILITY ID (HCFA OR FDA PROVIDED NUMBER)

3. USER FACILITY INFORMATION

a. Name

b. Street Address

c. City | d. State | e. ZIP Code

f. Country/Postal Code *(if not U.S.)*

4. USER FACILITY CONTACT INFORMATION

a. Name

b. Street Address

c. City | d. State | e. ZIP Code

f. Country/Postal Code *(if not U.S.)*

g. Telephone Number *(Include area code and extension)*

( )

5. TOTAL NUMBER OF REPORTS ATTACHED OR SUMMARIZED _____

a. Lowest Report Number _____ - _____ - _____
(HCFA or FDA Provided No.) *(Year)* *(Sequence No.)*

b. Highest Report Number _____ - _____ - _____
(HCFA or FDA Provided No.) *(Year)* *(Sequence No.)*

For each report in the range of report numbers listed above, attach a completed copy of Part 2 of this form, or a photocopy of the completed MedWatch FDA Form 3500A for the event that was sent to FDA and/or the manufacturer. In addition, attach a sheet listing report numbers in the above range that are not included in this report and explain why.

6. SIGNATURE OF CONTACT

7. DATE OF REPORT

__ __ / __ __ / __ __ __ __
M M D D Y Y Y Y

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0059)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

(Please **DO NOT** RETURN this form to this address.)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

MEDICAL DEVICE REPORTING
SEMIANNUAL USER FACILITY REPORT

PART 2 - SUMMARY OF EVENT

PART 2 INSTRUCTIONS

If photocopies of previously submitted FDA Form 3500A (MedWatch) are not provided for each MDR reportable event, complete one copy of the following for each MDR report submitted to FDA and/or the manufacturer during the six-month reporting period covered by this Semiannual Report.

1. USER FACILITY EVENT REPORT NUMBER

_____ - _____ - _____
(HCFA or FDA Provided No.) *(Year)* *(Sequence No.)*

2. WHERE WAS REPORT SUBMITTED? *(Check all that apply)*

☐ FDA ☐ Manufacturer ☐ Distributor ☐ Other _____

3. MANUFACTURER INFORMATION

a. Name

b. Street Address

c. City d. State e. ZIP Code

f. Country/Postal Code *(if not U.S.)*

4. DEVICE INFORMATION

a. Brand Name

b. Common Name

c. Model Number

d. Serial Number

e. Lot Number

f. Catalog Number

5. BRIEF DESCRIPTION OF EVENT

ABBREVIATED INSTRUCTIONS FOR FDA FORM 3500A SPECIFIC TO MEDICAL DEVICE REPORTING

GENERAL INSTRUCTIONS

1. Complete all sections and items that apply and type all entries.
2. Use the following codes when information is not available for any item: **NA** - not applicable; **NI** - no information yet but maybe later; **UNK** - unknown.
3. Enter dates in following format: **MM/DD/YY** (e.g., June 3, 1995 = 06/03/95. If exact date not known, provide best estimate. Use **YYYY** for year 2000 and beyond.
4. Enter the user facility report number or distributor report number and/or manufacturer report number in upper right corner of page 1. This has the format **NNNNNNNNNN-YYYY-XXXXX** where Ns represent the 10-character HCFA number of the user facility or the 7 digit registration or identification number of the manufacturer or distributor; **YYYY** is the year of the report and **XXXXX** is the 4 or 5 digit sequence number of the report for the reporting year (see 21 CFR 803 or guidelines).
5. Attach a continuation page(s) when entries exceed allowed space and indicate the report section and block number on each page.
6. Use the coding manual to complete blocks F10, H3, & H6. Ordering information for the Coding Manual, Document Number 799, is available by FAX at (800) 899-0381 or (301) 827-0111.
7. If more than one patient was involved in the same event, complete section A and blocks B2, B5, B6, B7, D10, and F10 for each patient. Enter the corresponding patient identifier in each block.
8. If more than one suspect medical device is involved, complete section D for each. Complete section F for one device and blocks F9, F10, F13 and F14 for each additional device. Pair each section D with its corresponding section F by marking each as follows: "Device 1", "Device 2", etc.

SPECIFIC INSTRUCTIONS

A. Patient information

A1 Use an identifier, do not use patient's name or SSN.

A2 Give patient's age or best estimate and indicate the time unit used (years, months, days).

B. Adverse event or product problem

B1 Check box 1 if adverse event and/or box 2 if product problem. Adverse event is used when reporting a death or serious injury. Product problem is used for a malfunction that could lead to a death or serious injury if it were to recur.

B2 Check appropriate event outcome. Check "disability" if the device may have caused or contributed to a permanent injury or impairment.

B5 Provide a complete description of event. Do not use the name of any person or institution. If space is inadequate, use continuation sheet(s) as necessary.

D. Suspect medical device

D The Suspect Medical Device is the device that may have caused or contributed to the MDR reportable event or the device that malfunctioned. It is important that the device be properly identified and that all applicable information in this block be completed.

F. For use by user facility/distributor-devices only

F2 Use the same report number as used on page 1 (see item 4 of General Instructions).

F7 If follow-up report, record the user facility or distributor initial report number in block F2 and the sequence number of this follow-up in the blank after "follow-up", e.g., for first follow-up enter "1", for second enter "2." Do not repeat previously submitted information on a follow-up report.

F10 Enter up to 3 "patient" and 3 "device" codes that most accurately describe the event. Place only one code in each box. Patient codes describe what happened to the patient as a result of the event and device codes describe device failures or problems during the event.

G. All manufacturers

G1 Enter the full name and address of the manufacturer reporting site (contact office) including contact name. The name and address of the manufacturing site, if different, must also be included in this block.

G3 Check source of reported information. If "literature" is checked, attach a copy of the article (in English) and record the literature citation in block H10. Check the "study" box when reporting an RPS/DPS study or postapproval study.

G5-6 Not for medical device use.

G7 Check "5-day" if five-day report, "Initial" if first or initial submission, or "follow-up" if follow-up or supplemental submission. If follow-up report, do not repeat previously submitted information. Place manufacturer report number of initial report in block G9 and the follow-up sequence number on the blank line in block G7 after "follow-up".

G8 Not for medical device use.

H. Device manufacturers only

H3 If device was evaluated, be sure to attach an evaluation summary.

H5 If the question is not relevant to the device (e.g., an x-ray machine), check "no".

H6 Codes must be entered for conclusions even if the device was not evaluated.

H7 Check all that apply.

H10 Enter any additional information, evaluation, or clarification. Do not duplicate previous information.

H11 Provide the following additional, corrected or missing information, identifying each data item by the applicable block and item number:

(1) any information missing on the user facility or distributor report, including any missing or incomplete event codes required by block F10,

(2) information corrected on the user facility or distributor report form after verification, including any corrected event codes required by block F10

(3) for each event code provided by the user facility or distributor in block F10, a statement of whether the type of event represented by the code is addressed in the device labeling, e.g., code # 1738 - labeled, code # 1701 - not labeled, and

(4) an explanation of why any required information was not provided and the steps taken to obtain such information.

Important information from FDA about Medical Device Reporting

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 of 1990 and the Medical Device Amendments of 1992.

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Also route to:
- ☐ Biomedical/Clinical Engineer
- ☐ Facility Administrator
- ☐ Nurse Administrator/Manager
- ☐ Quality Assurance Manager
- ☐ Risk Manager

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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ATTN: Editor, User Facility Reporting Bulletin

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