MEDICAL DEVICE REPORTING (FDA MEDICINE MANUFACTURERS)

User Facility Reporting

Issue No. 42 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Spring/Summer 2003

A FOND FAREWELL TO OUR READERS
LAST ISSUE OF THE USER FACILITY REPORTING BULLETIN!

Eleven years ago, we published the first issue of the User Facility Reporting Bulletin (UFRB) to assist hospitals, nursing homes, and other medical device user facilities in complying with the Medical Device Reporting (MDR) requirement of the Safe Medical Devices Act of 1990 (SMDA). We are sorry to announce that we will discontinue publishing the Bulletin.

Safe Medical Devices Act of 1990

SMDA imposed significant reporting requirements on facilities that use medical devices. Device user facilities such as hospitals, outpatient diagnostic and treatment facilities, and nursing homes were required to report device-related deaths, serious injuries and serious illnesses within ten days of the adverse event to the manufacturer, the Food and Drug Administration (FDA), or both. This was the first time these facilities were required to report to the FDA and manufacturers.

History of the UFRB

SMDA charged the FDA's Center for Devices and Radiological Health (CDRH) to inform user facilities how and when to comply with the various sections of SMDA.

In 1991, CDRH held seven conferences on MDR. CDRH staff presented information vital to participants on the reporting requirements and established contacts with CDRH staff who could help user facilities fulfill their reporting responsibilities.

CDRH asked the conference participants what would help them comply with the new law. Most participants said they would be better prepared to report device problems if they could receive feedback on reports received by CDRH. The participants said it would be helpful to learn what was happening in other facilities in the nation. In response to the suggestions from participants, we began publishing the User Facility Reporting Bulletin in the Spring of 1992.

Our commitment was to report on the safety of medical devices. We further committed the UFRB to provide information about

- problems encountered in mandatory reporting,
- suggestions for deciding what to report, and
- comments received from other readers.

Medical Device Amendments of 1992

In June of 1992, the Medical Device Amendments of 1992 (to the SMDA) became law. The amendments required that user facilities take their reporting one step further from any "information that reasonably suggests that **there is a probability** that a device has caused or contributed to a reportable event" to any "information that **reasonably suggests** that a device has or may have caused or contributed to a reportable event."

In This Issue:

FAREWELL - ***Continued***

Reminiscence

Then

To reminisce: our first issue in the Spring of 1992:

- introduced the quarterly UFRB and our logo to our readers,
- described SMDA,
- listed some Frequently Asked Questions (FAQs) received since mandatory reporting began (November 28, 1991),
- described the first 50 reports CDRH received,
- alerted the user facilities that the first semiannual reports were due, and
- published a calendar of meetings where CDRH would be exhibiting SMDA information, speaking, or both.

Now

Our Winter 2002 issue, featured articles on:

- retinal repair risks; needlesticks,
- results of FDA's survey of hospital reprocessors,
- FAQs on reprocessed single-use medical devices user fees,
- questions on registration and listing recently placed on the Reuse website,
- diathermy interactions with implanted leads as well as implanted systems with leads.

Eleven years later, we were still doing our job of providing feedback to our readers.

Discontinuing the UFRB

A few years ago, we began to evaluate the need to continue publishing the UFRB. We were sending 70,000 printed copies of the UFRB through the mail to hospitals, other types of user facilities, and to many individuals. Because of resource limitations, we reduced that number to 10,000 and finally decided to continue to publish online only.

Retrospectively, we affirmed that we had provided the necessary training and education for the user facilities to comply with the SMDA, MDR, and the Medical Device Amendments of 1992. Then, we began to focus more of our attention to providing feedback on adverse events as they were occurring.

In the past few years, we also began publishing information that was not directly related to user facility reporting. This additional information, however, had a direct effect on hospitals, the largest group of medical device user facilities. A prime example of the type of additional information we provided was the extensive attention we gave to the Reuse of Single-Use Devices (SUDs) issue.

After long and careful consideration, we decided that the UFRB had finally served its purpose, and the time had come to discontinue publishing. After 11 years, we end our publication with the Spring/Summer Issue, # 42.

Many of our readers have been with us from the beginning, and some of you have just recently discovered the UFRB. We are sorry that we will no longer be able to serve you.

In closing, we would like to thank you for supporting the Bulletin. We have enjoyed producing each issue, and we will continue to support FDA in its mission to promote and protect the public health.

The following presents ways that you can maintain your awareness of the medical device issues of interest to you.

KEEP CONNECTED WITH CONTACTS LISTING

FDA would like to invite you to be a part of the new and exciting Center for Devices and Radiological Health's (CDRH) Contacts Listing. The Contacts Listing is a tool that CDRH uses to inform people and organizations about medical device news and events that may be of interest to them. For example, if CDRH sponsors a public meeting to discuss policy issues or potential problems areas in your particular area of interest, we would inform you electronically.

Registration to the Contacts Listing is free. When you register, you may choose areas of interests, geographic region, specialties, and affiliations that best describe your interest as well as your organization's interests. You may also unsubscribe or update your information at any time. This is not a typical list service. You will not get messages on a routine basis. You will receive information only when it becomes available and only when it pertains to your areas of interest.

Here are some other examples of what CDRH will notify you about:

- teleconferences
- recalls and safety issues
- new websites
- statements of policy or guidance posted on CDRH web sites (e.g., *Federal Register* notices, press releases, and safety alerts)
- collaboration with CDRH on research of a particular issue

You can join by registering at: http://www.fda.gov/cdrh/contactslisting.

FDA/CDRH WEBSITES THAT MIGHT BE HELPFUL

21 CFR: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

510(k) Information & Releasable Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/search.cfm

Breast Implants: http://www.fda.gov/cdrh/breastimplants/

CDRH Databases: http://www.fda.gov/cdrh/databases.html

CDRH Home Page: http://www.fda.gov/cdrh/

CDRH Referral List: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfReferral/referral.cfm

CDRH Standards Program: http://www.fda.gov/cdrh/stdsprog.html

Cellular Phones: http://www.fda.gov/cellphones/

Code of Federal Regulations (CFR): http://www.fda.gov/cdrh/devadvice/365.html

Contacts Listing Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/contacts/Index.cfm

CT Scanning: http://www.fda.gov/cdrh/ct/

Device Advice: http://www.fda.gov/cdrh/devadvice/

Diabetes Information: http://www.fda.gov/womens/taketimetocare/diabetes/default.htm and http://www.fda.gov/diabetes

Electronic Products Radiation Control: http://www.fda.gov/cdrh/comp/eprc.html

FDA Home Page: http://www.fda.gov

Federal Food, Drug, and Cosmetic Act: http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm

Federal Science Website: http://www.science.gov

Freedom of Information: http://www.fda.gov/foi/foia2.htm

Global Harmonization: http://www.ghtf.org

Good Guidance Practices (GGP): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfggp/search.cfm

Human Factors/Use Error: http://www.fda.gov/cdrh/useerror/index.html

Index of CDRH Web Documents: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/topicindex/topindx.cfm

International Program: http://www.fda.gov/cdrh/international/

Lasik Eye Surgery: http://www.fda.gov/cdrh/LASIK/

Listing Searchable Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/Listing/search.cfm

Mammography: http://www.fda.gov/cdrh/mammography/

Medical Device Exemptions: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm

Medical Device Reporting Home Page: http://www.fda.gov/cdrh/mdr/index.html

Medical Device User Fee and Modernization Act of 2002 (MDUFMA): http://www.fda.gov/cdrh/mdufma

Office of In-vitro Diagnostic Evaluation and Safety: http://www.fda.gov/cdrh/oivd

Premarket Approval Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/search.cfm

Product Classification Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/search.cfm

Product Information Requests/FOI: http://www.fda.gov/cdrh/foicdrh.html

Recalls: http://www.fda.gov/cdrh/recalls/

Recently Approved Devices: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/MDA/mda-list.cfm?

Registration Searchable Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/registra/search.cfm

Reuse of Single Use Devices: http://www.fda.gov/cdrh/reuse/index.html

Safey Alerts and Public Health Advisories from FDA: http://www.fda.gov/cdrh/safety.html

Third Party Review Program: http://www.fda.gov/cdrh/thirdparty

SUBJECT MATTER INDEX TO UFR BULLETIN, ISSUES 1-42

SUBJECT **ISSUE**

SUBJECT **ISSUE**

SUBJECT **ISSUE**

User Reports

REUSE CD ROM AVAILABLE

The Center for Devices and Radiological Health developed a CD ROM entitled: **"An Overview of the Regulatory Requirements for Reprocessing of Single-Use Devices by Hospitals."** While supplies last, a free copy of the CD-ROM is available by request at http://www.fda.gov/cdrh/Reuse/reuse-messages.html.

The two-disc set covers the regulatory requirements that a hospital must meet if it reprocesses single-use devices (SUDs). Topics include:

- Introduction about reprocessing SUDs
- Registration and Listing
- Premarket Review
- Labeling
- Corrections and Removals
- Medical Device Tracking
- Problems with Reprocessing
- Medical Device Reporting
- Quality System Regulation
- Useful Information

To see the PowerPoint presentations from the CD ROM, visit the Reuse Web Page at: http://www.fda.gov/cdrh/reuse/reuse-documents.html#10.

Good-bye!

USER FACILITY REPORTING BULLETIN

FDA has produced the *User Facility Reporting Bulletin* quarterly 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, the Medical Device Amendments of 1992, and the Food and Drug Administration Modernization Act of 1997. The *Bulletin's* contents may be freely reproduced.

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