FOOD AND DRUG ADMINISTRATION

# MEDICAL DEVICE USER Facility Reporting

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## FDA INTRODUCES STUDY FOR USER FACILITY REPORTING

*by Susan Gardner, Ph.D.*

The current Medical Device Reporting (MDR) system for user facilities relies on healthcare professionals to recognize and then report to manufacturers serious device-related adverse events. [In cases of death, the manufacturer and the Food and Drug Administration (FDA) are notified.] FDA is concerned that this "passive" reporting system does not allow the agency to receive timely and accurate information about serious and potentially serious device problems.

To address this concern, FDA contracted a study of the feasibility of using a nationwide sample of user facilities to replace the current MDR system of universal reporting. The study is designed to identify barriers to user reporting; to assess the timeliness, completeness, and quality of the data received; and to determine the best approach for implementing a nationwide, active reporting system based on a representative sample of user facilities. The underlying assumption is that a representative sample of user facilities could serve the whole reporting universe and relieve other user facilities of the mandatory reporting obligation. FDA would be better able to educate and provide feedback to this smaller group of participants. The results would be an improved quality of data, an improved level of reporting, and a communication system that is beneficial to both FDA and the user facility community. *(Continued on page 2)*

## FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

*by Joseph M. Sheehan, Esquire*

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA). The law introduced wide ranging changes to the regulation of food, drugs, cosmetics, and medical devices.

Most provisions of the law went into effect 90 days after enactment, i.e., on February 19, 1998. The primary thrust of the law in the medical device area is toward streamlining the premarket review process, but there are other provisions in various areas. This article will focus on those provisions that affect device user facilities.

**Sentinel Reporting.** Section 213 of FDAMA requires the Food and Drug Administration (FDA) to plan and implement a program under which device user reporting would be limited to a subset of user facilities that constitutes a representative profile of user reports. During the planning phase of this program, usually referred to as Sentinel Reporting, **the present user facility reporting regulation will continue in effect**. After the program is fully implemented, the user facility reporting requirements will no longer apply to facilities not participating in the Sentinel Reporting program. *(Continued on page 3)*

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A contract for the study, called the Sentinel Surveillance Feasibility Study, was awarded in Fall 1996 to CODA , a small business in Bethesda, Maryland. During the first year of the 28-month contract, CODA conducted four focus groups that represented hospitals, nursing homes, and outpatient diagnostic and treatment facilities. CODA was investigating barriers to reporting adverse events in the current MDR system and incentives that might help in recruiting facilities for the study.

Starting in January 1997, CODA began site visits to selected user facilities. During these visits, CODA looked at the facilities' reporting systems and obtained direct feedback about problems in reporting. Based on information obtained from this exploratory work, CODA prepared a list of questions and issues to be addressed by FDA in the design of the Sentinel Study. CODA presented the final design of the study for approval to FDA in April 1997. As soon as FDA approved the study design, CODA immediately began developing materials (e.g., a brochure to describe Sentinel and its mission), more specific plans for recruiting (e.g., visits to prospective participant sites), and plans for the training of user facilities that agreed to participate.

As part of its contract, CODA developed a package for recruitment and a Memorandum of Understanding to be signed by each participating facility. A training package was developed for Sentinel participants that included a videotape and a training manual specifically to alert staff about possible medical device problems. By Fall 1997, 19 hospitals and 6 nursing homes had agreed to participate in the Sentinel Study. All have completed the obligatory training workshops.

FDA and CODA personnel will assist the facilities in the study with actual reporting (e.g., completing the form and selecting the correct

codes) and in developing their own in-service training program (using the video and manual described above). FDA will provide ongoing feedback on any MDR reporting problems. In turn, the facilities agreed to educate their personnel about reporting adverse events with medical devices and to send copies of all mandatory and voluntary reports to CODA. All data submitted to CODA will be stripped of identifiers and entered into a separate database.

Evaluation of the Sentinel Study will be both quantitative and qualitative. Data submitted to CODA will be evaluated on several quality measures and then compared to data submitted to FDA from users not participating in the study. The small number of participating facilities will limit quantitative evaluation, but FDA will attempt to compare reporting rates of the study facilities to non-study facilities. FDA will look specifically at reports related to issues previously identified as areas of concern. Finally, during the last phase of the study, participants will convene in a workshop setting to provide feedback, based on their experiences during the study. Discussion of issues related to establishing an excellent nationwide Sentinel Reporting program will be the major objective of the workshop.δ

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Susan Gardner, Ph.D., is Deputy Director of CDRH's Office of Surveillance and Biometrics.

Coming in the Spring Issue:

An article on how to preserve evidence for an investigation of an adverse incident.

**Food And Drug Administration Modernization Act Of 1997 -** *(from page 1)*

By November 21, 1999, FDA must report to Congress on its progress in implementing this program. Further information on Sentinel Reporting will appear in future issues of the *Bulletin*. (See related article: *FDA Introduces Study for User Facility Reporting* by Susan Gardner, Ph.D., on page 1)

**Semiannual Reporting.** Section 213 also replaces the semiannual summary reporting requirement for user facilities with an annual requirement. After the January 1, 1998 semiannual report, the next summary report will be an annual report required on January 1, 1999.

**Report Disclaimers.** Section 420 provides that any entity required to submit a report concerning the safety of a product need not admit, and may deny, that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or caused or contributed to a death, serious injury, or serious illness.

**Device Tracking.** Section 211 revises the device tracking requirements. FDA may order a manufacturer of a class II or class III device to track the device if its failure would be reasonably likely to have serious adverse health consequences, if the device is intended to be implanted in the human body for more than one year, or if it is a life-supporting or life-sustaining device used outside a user facility. FDA held a public meeting on this issue and on the postmarket surveillance provisions of the new law on January 15, 1998, in Rockville, Maryland. On February 11, 1998, FDA notified manufacturers to continue tracking their devices until FDA notifies the otherwise. FDA also plans to publish a *Federal Register* notice requesting comments on which devices should be tracked. In the future, FDA may revoke some orders already issued.

**Confidentiality of User Reports.** FDAMA has provided additional protection of the confidentiality of user facilities that make reports. Section 213 eliminates section 519(b)(2)(c ). Under the old provision, FDA was not obligated to protect the confidentiality of a user facility if the user facility report was submitted as part of the manufacturer's event report. Because a manufacturer was required to submit the user facility report as part of its report, user facility names were routinely available. Under the revised provision, user facility names will be available only in an action for a violation of the reporting requirements or in a communication to the manufacturer of the device. See our web page at **http:www.fda.gov/cdrh** for more information about FDAMA.δ

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Joseph M. Sheehan, Esquire, is Chief of the Regulations Staff in CDRH's Office of Health and Industry Programs.

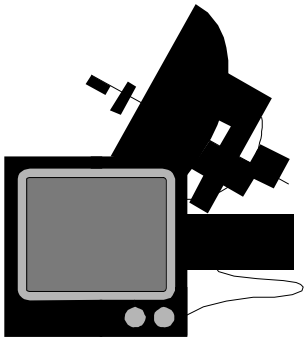

## *User Facility Reporting Bulletin*

FDA produces 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. Comments should be sent to the Editor.

Editor: Nancy Lowe
Assistant Editors: Herb Spark
Mary Ann Wollerton
Design: Edie Seligson

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health, HFZ-230
Rockville, MD 20857
FAX: (301) 594-0067
E-mail: nsl@cdrh.fda.gov



# Natural Rubber/Latex Allergy:

## Recognition, Treatment, and Prevention

**Live Satellite Videoconference to Be Broadcast in US & Canada**

Tuesday, May 5, 1998, Broadcast Time 1:00 p.m. – 4:15 p.m. ET

Produced by FDA's Center for Devices and Radiological Health (CDRH), Division of Communication Media

Check the videoconference WEB page for the most current information at **http://latex.fdli.org**

### Overview

Natural rubber/latex allergy is an emerging public health issue which impacts a wide range of healthcare and workplace practices. Allergy to natural rubber/latex containing materials can result in serious health problems. Healthcare providers need to know how to accommodate individuals with natural rubber/latex allergy and how to minimize the possibility that they or their patients may become sensitized. Managers of workers routinely exposed to natural rubber/latex-containing products in all occupational settings need to be able to recognize symptoms of natural rubber/latex allergy and to minimize the possibility of worker sensitization.

During the live, interactive broadcast, a panel of internationally recognized experts will provide up-to-date information about the identification, management, and prevention strategies appropriate for both healthcare and occupational settings. The faculty represents major healthcare professional organizations, occupational health and safety professionals, and medical/dental device manufacturers. Viewers may phone or FAX questions throughout the broadcast.

### How to View the Broadcast

There are two ways you can view this program:

(1) You can watch the program broadcast at an "open" downlink viewing site that may be able to accommodate you.

- Consult the Natural Rubber/ Latex Videoconference web page at http://latex.fdli.org for a list of registered open sites that have offered to accommodate additional viewers in your locality. Contact the site coordinator listed for further information on any particular site. *Please note: Some open sites may charge you a fee to cover their costs. Possible hosts for open downlink sites are:*

- State and local professional associations;
- State and local health departments;
- Local American Red Cross; and
- Local hospitals and fire and rescue stations.

(2) You or your facility can arrange to host your own downlink viewing site. To locate a suitable downlink site, check first with your own audio/visual department. You can also contact your local community college or university, hotels, state and local health departments, fire and rescue stations, sports restaurants, or extension service offices for information about setting up a viewing site at one of these facilities. The site must have a C-band or Ku-band satellite dish. There is a fee to register the site.

### CE Credit & Site Registration

Continuing education (CE) credit is available to all who qualify and register prior to the broadcast, pay a small fee, view the live broadcast, and return a brief evaluation form.

To register a downlink site or to apply for CE credit, mail or FAX your form(s) and payment(s) to:

Raffa & Associates, PC
VIDEOCONFERENCE
1899 L Street, NW, Suite 600
Washington, DC 20036
FAX: (202) 822-0818

You can also register online at:
**http://latex.fdli.org**

A four-page brochure about the latex teleconference, including forms, is available through FDA's automated FAX system, Facts-On-Demand (FOD), at:

1-800-899-0381

At the first voice prompt, press 1 to access FOD; at the second voice prompt, press 2 and then enter 378 followed by the pound sign (#).

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