MEDICAL DEVICE REPORTING (FDA MEDICINE MANUFACTURERS)

# User Facility Reporting

Issue No. 37 *A quarterly bulletin to assist hospitals, nursing homes, and other device user facilities* Winter 2001

## CHANGE IN ENFORCEMENT DEADLINE FOR REPROCESSED CLASS II SINGLE-USE DEVICES

The Food and Drug Administration (FDA) announced on February 14, 2002, a change in the enforcement deadline for class II reprocessed single-use devices (SUD) and reminded hospital SUD reprocessors of the agency's enforcement policy for premarket requirements as follows:

- **Class II Devices***

FDA is extending the deadline for active enforcement of premarket notification submission requirements for class II SUDs until August 14, 2002, provided that the reprocessor:

1. submitted a premarket notification submission (also known as a "510(k) submission") by August 14, 2001;
2. has not received a *not substantially equivalent determination*; and
3. provides timely responses to FDA's requests for additional information per 21 CFR §807.87(l).

- **Class III Devices**

FDA may actively enforce premarket approval requirements for class III SUDs on February 14, 2002.

- **Class I Devices***

FDA may take enforcement action against any class I SUD if:

1. a 510(k) submission has not been submitted to the agency by February 14, 2002, or
2. if the class I device does not have FDA marketing clearance by August 14, 2002.

*Other than the class II and class I devices that are exempt by regulation from the 510(k) requirements of the Food, Drug, and Cosmetic Act.

## AAMI SEMINAR FOR HOSPITALS THAT REPROCESS SINGLE-USE DEVICES

The Food and Drug Administration (FDA) has contracted with the Association for the Advancement of Medical Instrumentation (AAMI) to provide training for hospitals that are reprocessing single-use devices (SUDs). A 2-hour live virtual seminar is being offered on March 7, 2002, 11:30 a.m. - 1:30 p.m. EST. The seminar will cover essential FDA regulations pertaining to the reprocessing of SUDs such as:

- Establishment registration and device listing
- Premarket notification (510(k)) and premarket approval (PMA)
- Quality System regulation
- Labeling
- Corrections and removals
- Device tracking
- Medical Device Reporting (MDR) regulation

See the AAMI flyer on page 2 for additional information about the seminar.

### In This Issue:

## AAMI Virtual seminar for Hospitals

# FDA Regulations

## for Reprocessing Single-Use Devices

March 7, 2002, 11:30 am - 1:30 pm EST

This seminar is a 2-hour live virtual seminar on FDA regulations for hospitals and other institutions that are currently reprocessing single-use devices (SUDs) or thinking about reprocessing in the future. This program is offered only once, so be sure to mark your calendar.

### BACKGROUND

In August 2000, the FDA released a final guidance on the practice of reprocessing and reusing medical devices that are intended to be used only once entitled, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." In this document the FDA states that hospitals and third parties that reprocess SUDs will be regulated in the same way as original equipment manufacturers. This means that hospitals, whether reprocessing SUDs in-house or outsourcing reprocessing activities to a third party, are subject to the requirements of the Food, Drug, and Cosmetics Act just as manufacturers are.

In light of these requirements, the FDA has contracted with AAMI to develop this virtual seminar so that you can better understand the regulations. Organizations supporting AAMI in offering the seminar include the Association of Medical Device Reprocessors and the American Society for Healthcare Central Service Professionals.

### WHY YOU SHOULD PARTICIPATE

This interactive and dynamic 2-hour seminar will cover essential FDA regulations pertaining to reprocessing of SUDs and important information that you and your hospital need to know about compliance. Learn about:

- Registration and listing
- Good manufacturing practice (GMP) under the Quality System
- Submission of adverse events reports under the Medical Device Reporting (MDR) regulation
- Device tracking
- Corrections and removals
- Premarket notification and approval
- Information necessary for the completion of each requirement
- The legal and regulatory implications of reprocessing
- Your hospital's potential liability exposure when contracting the reprocessing function to a third party
- Strategies for compliance

### FACULTY

Thomas Muldoon, a member of the law firm Bell, Boyd & Lloyd, LLC, will be the featured presenter for this program. A noted and recognized speaker on the subject of Food and Drug law, Mr. Muldoon is an adjunct professor at both DePaul University and Loyola University School of Law.

**For registration information please visit the AAMI web site:**

http://www.aami.org/meetings/reuse/virtualreg.html

# USING DENTURE CLEANSERS SAFELY*

*By Janie Fuller, DDS, MPH*

***Editor's Note: This article is particularly relevant for our readers who care for elderly patients.***

Improper use of denture cleaners can have serious consequences as evidenced by the following cases reported to the Food and Drug Administration through its Medical Device Reporting (MDR) System.

***Case 1:*** An 81-year-old man soaked his dentures in an over-the-counter (OTC) denture cleanser and then gargled with the remaining solution. His tongue became swollen and blue. Despite emergency efforts that included CPR and administration of isosorbide dinitrate, he died at the scene.

***Case 2:*** An 84-year-old woman with a history of Alzheimer's dementia, confusion, and paranoia ate one tablet of an OTC denture cleanser. Afterward, she vomited a green substance, became delirious, and required treatment in the emergency department.

***Case 3:*** A 74-year-old nursing home resident with bronchitis ate about six denture cleanser tablets. She was found foaming at the mouth and having difficulty breathing. Her esophagus was irritated and her chest distended. After suffering cardiopulmonary arrest, she received CPR, was admitted to the hospital, and survived.

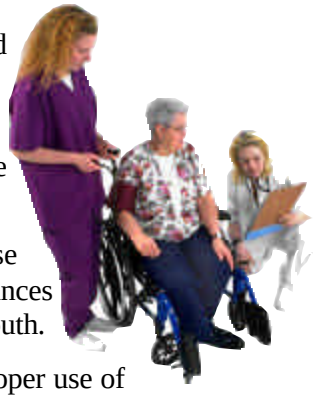
**What went wrong?**

Denture cleansers are not intended for internal use, but in the above cases, they were **gargled** or **swallowed**. Some OTC denture cleansers contain ingredients associated with allergic reactions[1], including anaphylaxis. Other ingredients may irritate mucosa and may be toxic if ingested.

**What precautions can you take?**

When your patients use denture cleaners, take these steps:

- Carefully monitor your patients use of denture cleansers, especially those patients who may have difficulty reading or understanding label warnings and cautions, as well as patients who are confused or have Alzheimers' Disease.
- Teach them to carefully read all denture cleanser labels and heed all warnings and cautions.
- Warn them never to **chew, swallow, or gargle** with denture cleansers.
- Remind them to thoroughly rinse dentures and other dental appliances before placing them into the mouth.
- Remind your patients that improper use of denture cleaners may cause serious consequences.



**Reporting Adverse Events**

Although you are encouraged to follow your facility's adverse event reporting requirements, you may voluntarily report medical device problems to FDA's MedWatch program. Reporting will help to identify and address device-related public health issues:

- By telephone, call 1-800-FDA-1088
- By FAX, send Form 3500 to 1-800-FDA-0178
- By mail, send Form 3500 to MedWatch, Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20857-9787
- Electronically, send to http://www.fda.gov/medwatch/index.html

**Reference**

[1]LeCoz, C., and Bernard, M.: "Allergic Contact Cheilitis Due to Effervescent Dental Cleanser: Combined Responsibilities of the Allergen Persulfate and Prosthesis Porosity," *Contact Dermatitis*. 41(5):268-271, November 1999.

Janie Fuller, DDS, MPH, is the Director, Regulatory Review Office, in CDRH's Office of Surveillance and Biometrics.

** Adapted from Nursing 2001, Volume 31, Number 12.*

## ELECTRONIC NOTIFICATION FOR THE *USER FACILITY REPORTING BULLETIN* IS NOW AVAILABLE

**If you would like to be notified electronically (via e-mail) when a new issue of the *User Facility Reporting Bulletin* is released, you can sign-up for our List Service at:**

**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCDRHNew/listman.cfm**

**Please share this information with your colleagues. They'll thank you for it!**

## FDA IS SEEKING COMMENTS AND SUGGESTIONS ON LABELING OF REPROCESSED SINGLE-USE DEVICES

The Food and Drug Administration (FDA) plans to develop guidance on how reprocessed single-use devices (SUDs) may be labeled, including whether the original equipment manufacturer's (OEM) trademark or name should remain on the reprocessed device along with the identity of the remanufacturer (i.e., reprocessor). FDA invites comments and suggestions on the content of the guidance document. A notice entitled Medical Devices; Guidance on Labeling of Reprocessed Single Use Devices; Request for Comments and Information was published in the December 20, 2001 *Federal Register* (http://www.fda.gov/OHRMS/DOCKETS/98fr/122001a.pdf).

**Background**

The Association of Disposable Device Manufacturers requested in a citizen's petition (March 22, 2001) that FDA:

1. require reprocessors of SUDs to remove the OEM trademark from the devices and any reference to the OEM in the labels of the devices;
2. take actions to identify and enforce this requirement; and
3. refuse to approve premarket submissions (marketing clearance) unless the applicant represents that the device will meet this requirement.

On September 17, 2001, FDA denied the petition because it believed that any misleading implications from the OEM's labeling could be remedied by the reprocessor providing additional information about its responsibility for product problems. FDA also said that it would publish a guidance document that will recommend more specific language and directions on the matter. ❁

## USING STANDARDS IN PREMARKET SUBMISSIONS FOR REPROCESSED SINGLE-USE DEVICES

Standards may be as useful in premarket notification (510(k)) submissions for reprocessed single-use devices (SUDs) as they are for 510(k)s from original equipment manufacturers. The following documents explain FDA's policy about the use of standards.

- *Use of Standards in Substantial Equivalence Determinations* explains how consensus standards may be used in 510(k)s including those for reprocessing of SUDs. The document is available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/1131.html.
- *Recognition and Use of Consensus Standards; Final Guidance for Industry and Staff* provides guidance to FDA staff and industry on the recognition and use of national and international standards, including declarations of conformity to these standards during the evaluation of all premarket submissions. The document is available from the Internet at: http://www.fda.gov/cdrh/ost/guidance/321.html

Standards recognized by FDA that may be useful to reprocessors of single-use devices, such as those for sterilization, biocompatibility, and safety/performance, can be found by searching the Standards web site at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. ❁


### 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.

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