



*Excerpts from Statement of*  
**Daniel Schultz, M.D., Director, Center for Devices and Radiological Health, FDA**  
before Committee on Government Reform, House of Representatives on September 26, 2006

## **INTRODUCTION**

FDA has been actively engaged in the single use device (SUD) reuse issue for some time, and our efforts have included research, outreach, pre-market review, inspections, and compliance investigations. We have held numerous public meetings and conferences with industry, healthcare professionals, and consumers over the years to determine the extent, magnitude, and changing nature of this practice. FDA has carefully evaluated and conducted research to develop the scientific basis for addressing SUD reprocessing. We have inspected third party reprocessors, evaluated and investigated reports of patient injuries, and reviewed numerous pre-market submissions. Taken together, the Agency believes that these efforts have provided, and will continue to provide, reasonable assurance of safety and effectiveness of reprocessed SUDs for patients.

## **THE REGULATION OF REPROCESSED SINGLE USE MEDICAL DEVICES**

The reprocessing of SUDs is legally permissible in the United States under the FD&C Act. Currently, only Class I and II SUD device types have been cleared by FDA for reprocessing. No Class III SUDs have been cleared/approved for reprocessing. Prior to issuance of this guidance, reprocessing of SUDs was frequently performed by hospital personnel without regulatory oversight or regard to the level of device risk. In addition, many third party reprocessors contracted with hospitals to perform similar tasks and these contractors did not consistently adhere to FDA's Good Manufacturing Practice Requirements.

## **CHANGES ENACTED WITH MDUFMA**

In 2002, with enactment of the Medical Device User Fee and Modernization Act (MDUFMA), Congress mandated a number of new requirements for SUD reprocessors including, for certain SUDs, the pre-market submission of data to the Agency that exceeded the requirements for original manufacturers (OEMs). In addition to the requirements specified in our 2000 Guidance Document, certain reprocessed SUD types that potentially could pose the greatest risk of infection and inadequate performance following reprocessing and that were previously exempt from any pre-market submission requirements, are no longer exempt. In addition, MDUFMA required a change to FDA's MedWatch voluntary and mandatory reporting forms (Forms 3500 and 3500A, respectively) to facilitate the reporting of adverse events involving reprocessed SUDs. Finally, MDUFMA required, as of August 1, 2006, that reprocessed SUDs prominently and conspicuously bear the name, abbreviation, or symbol of the reprocessor on the device itself, on an attachment to the device, or on a detachable label, depending on the physical characteristics of the device and whether the device has been marked by the OEM.

## **COMPLIANCE ACTIVITIES**

FDA's inspectional program serves as a bridge between pre- and post-market activities. Since 2000, on average, FDA has conducted inspections of reprocessor firms once every two years, a rate considerably higher than the one inspection in four years for OEMs. Of the seven firms currently known to be reprocessing, all have been inspected within the last two years. FDA continues to evaluate newly registered firms to confirm whether they are performing SUD reprocessing and updates its inspectional plan as required.

## **POST-MARKET SURVEILLANCE FOR REPROCESSED SUDs**

Post-market monitoring of device-related adverse events (AEs) and product problems is accomplished through the Medical Device Reporting (MDR) system. MDR reports include deaths, serious injuries, and device malfunctions. Healthcare facilities are required to report deaths suspected to be device-related to both FDA and the manufacturer/reprocessor. They are required to report serious injuries to the manufacturer/reprocessor. ... The final analysis of the reports found that the types of adverse events reported to be associated with the use of SUDs were the same types of events that also are being reported for new, non-reprocessed devices.

## **FEEDBACK FROM A SAMPLING OF MEDSUN HOSPITAL FACILITIES THAT USE REPROCESSED SUDs**

FDA's Medical Product Safety Device Network (MedSun) is comprised of over 350 hospitals that have been recruited and specifically trained to identify and report device problems. ... None of the participants we spoke with reported specific problems with SUD-related infections. ... It also is interesting to note that the participants did not report a greater concern with mechanical problems associated with reprocessed SUDs compared to un-reprocessed SUDs. In general, the participants had a favorable view of reprocessed SUDs used in their facilities.

## **CONCLUSION**

Available data show that SUDs can be reprocessed with a reasonable assurance of safety and effectiveness. FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device. The law and regulations in place are designed to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on sound science. FDA continues to monitor the performance of these devices and to assess and refine our ability to regulate these devices appropriately.