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# **MDUFMA Stakeholders Meeting – Reprocessing of Single-Use Devices (SUD's)**

**November 17, 2005**

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# Outline

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- Significant Progress
- Lingering Challenges
- Follow-Thru



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# Significant Progress

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- Congressional Mandate (MDUFMA)
- Revisions to Medwatch form
- Numerous Guidance Documents
- Supplemental Validation Reviews
- Exemption Terminations
- Labeling (MDUFSA)



- Continued review and termination of exemptions for Class I SUD's when reprocessed:
  - Stone Dislodgers
  - Orthodontic Brackets
- Continued review and calls for Supplemental Validation data:
  - Heart Stabilizers
  - Endoscopic Accessories



- Pressure from Stakeholders
- Education
  - If an SUD fails after it has been reprocessed – there can be no underlying problem with the original device!
  - If a reprocessed SUD fails or there is an event – the report must always go to the Reprocessor!
- Proper MDR Reporting
  - Inherent disincentive for User Facilities
  - Lack of awareness of whether device was reprocessed



- Implementing Congressional Intent as captured in the MDUFSA Senate Report...

***“Finally, reprocessed single-use devices are not generally marked to identify their reprocessor. Adverse events associated with a reprocessed device may therefore be misattributed to the original manufacturer, and not to the reprocessor. In addition, when reporting adverse events, health care providers may mistakenly believe that the device is a new, unused product from the original manufacturer of the device, and not from a reprocessor. In 2002, the provisions in Section 301 of MDUFMA, which were intended to lead to the marking of reprocessed single-use medical devices, created concerns regarding both the feasibility and timing of implementation.”***



- ***“The committee believes it is essential to require the specific identification of reprocessed versions of single-use devices to ensure that physicians, nurses, users, and hospital administrators know that a device they have used was reprocessed.”***
- ***“This reporting requirement is the cornerstone of FDA's post-marketing surveillance system for medical devices, and it cannot work as intended unless health care providers, original manufacturers, device reprocessors, and FDA can readily and accurately identify when a single-use device has been reprocessed.”***



- ***“...there is evidence to indicate that the lack of specific labeling to identify reprocessed devices may lead to inadequate reporting of patient injuries and product malfunctions involving reprocessed single-use devices, particularly where a reprocessed device bears only the mark of the original manufacturer.”***
- ***“...This undermines the purpose and effectiveness of section 519 of the FFDCA and FDA's MDR regulations, leaving FDA with a less accurate picture of the post-market safety and effectiveness of these devices.”***



- ***“The committee therefore believes there is no reason for FDA to delay implementation of section 502(u) or to elect to exercise enforcement discretion in the face of non-compliance with its requirements.”***
- ***“...Although section 502(u) will first become effective 12 months after the legislation is enacted, the committee believes that it is clear how this section applies to the vast majority of reprocessed devices, and the committee expects reproprocessors to implement its requirements as soon as possible for the devices they reprocess, in the best interest of post-market surveillance and the public health.”***



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# In Summary...

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- Great Progress
- Challenges Remain
- Patient Safety Must Always Be First