



Surgical Instrument Service & Sterilization

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November 28, 2005

Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20857

**Docket No. 2005N-0389, DOCID: fr29se05-52**

To Whom It May Concern:

This letter is in response to the Agency Information Collection Activities; Proposed Collection; Comment Request for Reprocessed Single Use Device Labeling, docket number 2005N-0389. MediSISS would like to request clarification in the Draft Guidance on the following areas in order to ensure compliance with section 502(u) of The Act (21 U.S.C. 352) amended by Medical Device User Fees and Modernization Act of 2002, amended by section 2 (c) of The Medical Device User Fee Stabilization Act of 2005.

Under the amended provision, the reprocessor is required to “identify itself by name, abbreviation, or symbol in a prominent and conspicuous manner on the device or attachment to the device”. MediSISS would like clarification on the word “attachment”. Is the labeling required to be a permanent fixture on the device? Can an attachment be a removable sticker? Are there permissible ways in which a device can be tagged? As labeling cannot interfere with functionality, can a tag be removed?

In addition, does the labeling apply to all device classes I, II and III? Will the Agency require submission of validation data for the labeling?

Lastly, is the reprocessor of single use devices required to register or trademark their “mark” with the appropriate agencies? Does the label have to match the company colors or can the label be monochrome, black and white contrast?

Thank you for your help in clarifying the requirements of the amended provisions to ensure full industry compliance.

Best regards,

Brandi James  
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