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Division of Dockets Management  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD  
20850

**Docket Number 2005D-0401; Comments on Draft Guidance for Industry and FDA Staff: *Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended – Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices***

To Whom It May Concern:

The following comments are offered on the above-entitled Draft Guidance Document:

1. **Re: "V. When is this new labeling Requirement Effective?"**

In answering this hypothetical question, you present two possible scenarios. In the first scenario, you make reference to a July 1, 2006 date which we do not understand. Was this date merely intended to represent any date prior to August 1, 2006, the statutorily mandated effective date, or is there significance to the date?

In the second of the two examples, the device begins to bear the original manufacturer's mark prominently and conspicuously after August 1, 2006. In this case, according to the draft Guidance, the reprocessor must immediately begin to add a prominent and conspicuous mark to the device or an attachment.

This interpretation is faulty. The law allows 12 months after the effective date. Consequently, you should be interpreting this to mean that not later than 12 months after the OEM initiates prominent and conspicuous labeling, the reprocessor must initiate prominent and conspicuous labeling. Without a transition period, you are *de facto* requiring reproducers to initiate prominent and conspicuous labeling in order to avoid noncompliance – in the event a manufacturer implements labeling.

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By way of example, consider this hypothetical situation: A device manufacturer does not begin to label a single-use device prominently and conspicuously until September 1, 2006 (the effective date of the law). On September 10, 2006 (or any later date), a reprocessor receives two devices from a hospital customer. Both were manufactured by the same OEM – one on August 31, 2006 and the other on September 1, 2006, used by the hospital customer, and sent to the reprocessor.

Clearly, under Section 301, only the device manufactured on September 1 requires additional labeling. However, in order to be able to reprocess the device and return it to the customer, the reprocessor must have 'prominent and conspicuous' labeling developed, validated and waiting for implementation – or implemented in advance.

We respectfully request you to reinterpret the law to allow a transition period for prominent and conspicuous labeling by reproducers.

**2. Re: "VI. When should a reprocessor place its mark on a device, use a detachable label, or use an attachment?"**

In your explanation of the law, you offer the recommendation that the detachable label contain a statement directing a practitioner to remove the detachable label and affix it to the patient's medical record.

The wording of the law stops well short of requiring the detachable label to bear instructions for placing the label in the patient records. As such, it is inappropriate for the Guidance Document to make this recommendation.

A corollary circumstance is the detachable label included with a device when FDA orders tracking, or the chart stickers included with an implantable device. In neither case does FDA include a Guidance Document recommendation that the stickers include a statement directing it to be removed and included in the patient records.

Any device sticker, whether for a new or reprocessed device, is generally ruled by hospital risk management professionals, and in our experience, many have implemented policies in opposition to placing these identifiers in patient records.

This statement should be deleted.

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**3. Re: Obliterating the Original Manufacturer's Mark**

There is no discussion in the Guidance about the reprocessor obliterating the original manufacturer's mark. However, as frequently as this comes up, it would be most appropriate for FDA to address.

On September 21, 2001, FDA issued a letter denying a Citizen's Petition filed by the Association of Disposable Device Manufacturers (ADDM; Refer to Docket # 01P-0148). In that petition, ADDM specifically requested FDA to require the marks of original manufacturers to be obliterated by reproprocessors.

We regard this as a precedent, and request that FDA add language to the Guidance that is consistent with the language of the denial letter.

**4. Re: Is a Blinded Study a Significant Risk Study?**

We respectfully request FDA to add language to the Guidance that allows an exemption from device marking for the purpose of comparative study. If an interested party desires to design and conduct a blinded study that compares the use of new and reprocessed devices, the requirement for device marking will make blinding difficult to impossible. The current mechanism for exemption is the Investigational Device Exemption (IDE) although it is unlikely FDA wants these studies to be designated as Significant Risk studies.

Therefore, we request FDA create a mechanism to allow blinded comparative studies of new and reprocessed devices to proceed without an IDE requirement.

We believe the comments offered are reasonable, lawful, and enhance the meaning of the Guidance Document.

With best regards,



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Regulatory Affairs and Quality Assurance  
Alliance Medical Corporation