COALITION OF

Wound Care Manufacturers

May 9, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, Maryland 20852

Dear Sir/Madam,

On behalf of the Coalition of Wound Care Manufacturers ("CWCM"), I am submitting comments related to "510(k) Implementation: Discussion of an On-line Repository of Medical Device Labeling, and of Making Device Photographs Available in a Public Database Without Disclosing Proprietary Information." The CWCM represents leading manufacturers of surgical dressings, negative pressure wound therapy and other medical devices and supplies used by Medicare beneficiaries for the treatment of wounds.

Having attended the April 7th FDA Public Meeting and the opportunity to sit on the panel discussion, I can understand how having a FDA on-line repository of medical device labeling might be helpful to caregivers and patients; however, device manufacturers are very concerned about various aspects of this and would ask that the FDA proceed cautiously before implementing this initiative. The CWCM agrees with some of the recommendations made at the FDA Public Meeting which stated that the information that might be contained in the repository is the same information that is in the manufacturers' current website and if such a repository is established, there should be linkage to this.

The CWCM had the following questions and concerns:

1. Which devices would be selected for the repository? It would seem that FDA should define who would benefit the most from the use of this repository. From the FDA Public Meeting, it seemed that patients, caregivers, clinicians and physicians would benefit from seeing home care devices and products in the repository. However, the CWCM questions whether disposable Class I products that are commodity products should be included since in photographs they look very similar and their uses are also very similar.
2. What would be FDA's criteria for updating the repository when the manufacturer would need to update the labeling? For a manufacturer who has hundreds of types of catheters or surgical dressing or other accessories again that are a Class I disposable device, this requirement would be extremely burdensome especially if photographs needed to be updated. These activities would warrant the manufacturer adding additional staff to comply with this.

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3. The FDA might also want to recognize that this may also be burdensome to manufacturers of privately labeled devices, reprocessed devices and refurbished devices. These manufacturers do not really hold the labeling for these devices and would still need to be responsible in some manner.
4. How would the FDA make the public and health care professionals aware of this new repository? We had concerns that caregivers and patients would not know where to go to look for the repository and may not know it exists. Many times caregivers will call the local DME provider and look at their catalogs when they need to identify products or devices.
5. The CWCM is also concerned that devoting scarce resources to establishing and maintaining this new repository might impact the Agency's clearance and approval process performance and would recommend that its efforts be concentrated in those important endeavors.

We appreciate the opportunity to comment on this issue and are willing to work with the Agency as a resource in thinking through the establishment of this new initiative.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director