COALITION OF

Wound Care Manufacturers

September 1, 2016

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

Submitted electronically to www.regulations.gov

Re: Docket Number FDA-2016-N-2147 General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting: Establishment of a Public Docket; Request for Comments

Dear General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee;

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit the following comments in response to the September 20-21, 2016 Food and Drug Administration's (FDA) meeting of the General and Plastic Surgery Devices Panel ("Panel") of the Medical Devices Advisory Committee. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. This Panel meeting is of particular interest to us as many of our members manufacture antimicrobial wound care products which are the subject of these discussions.

It is our understanding that the purpose of this meeting is for the FDA to convene the Panel so as to obtain recommendations about the classifications of devices that are wound dressings combined with drugs which the FDA has groups under the FRO product code. As we will state in further detail during the September 20-21 meeting, the Coalition believes that the products that are currently in the FRO category are low to moderate risk, have been in the marketplace for many years, and should be classified by the FDA into either Class I or Class II, most remaining subject to 510(k).

We are members of the Alliance of Wound Care Stakeholders and are in agreement with the comments that they submitted which included such topics as: the science of management of chronic wounds, information regarding antimicrobial wound care products, safety and effectiveness of products in the FRO category and their indications for use.

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SPECIFIC COMMENTS

FRO products currently classified into class II category should continue to require 510k clearance and the current kind of testing can be made into special controls to assure that the products remain safe and effective

Currently, the products in the FRO category are cleared through the 510(k) premarket notification process. In the 510(k) process, the sponsor must demonstrate that the proposed device is as safe and effective as a legally marketed predicate device. A typical 510(k) for a product with wound management and antimicrobial barrier/colonization claims, will include a detailed description of the device technology, a statement of the indications for use, draft labeling and the scientific evidence necessary to demonstrate substantially equivalent safety and effectiveness to the legal predicate device. Safety evidence generally includes toxicological risk assessment and in vitro and/or in vivo biocompatibility studies.

In some circumstances, animal studies may also be conducted. Regarding performance and effectiveness, the 510(k) will generally contain bench testing as applicable to the device. Examples include but are not limited to, exudate management, microbial barrier effectiveness, broad spectrum microbial effectiveness and antimicrobial release testing. FDA has the authority to establish Special Controls for Class II devices, e.g., guidance documents which clarify the minimal requirements that FDA expects in a 510(k) as premarket evidence. In addition, FDA has authority to require additional post market clinical studies for certain circumstances as a condition of 510(k) clearance.

The Coalition believes that the current 510(k) process has proven over the past 40 years to provide sufficient controls for these low to moderate risk device types and that they should remain as Class II medical devices since the risks are well understood and they ae controlled. However, the FDA may want to consider whether there may be some appropriately placed in Class I and exempt from 510k for example those that are OTC and comprised of well characterized agents.

FDA Might Want to Establish Different Categories for Various Types of Products in the FRO Category

The Coalition members reviewed the over 400 products currently listed in the FRO category and found the category contains many diverse product groups with different indications for use as identified in their 510ks. They include both OTC and prescription products as well. The products could be categorized as follows:

- Antimicrobial dressings and gels that contain such ingredients as silver, honey, polyhexamethlene biguanide (PHMB)—some are used for management of wounds and others for catheter sites

- Antimicrobial wound care solutions that are used for cleansing, irrigating, moistening, and debriding- to remove wound debris from acute and chronic dermal lesions that are partial or full thickness wounds- and that contain such ingredients as: hypochlorous acid (HCIO) and silver.
- Dressings that are indicated for management of wounds but do not contain antimicrobials
- Saline solutions
- Hemostatic agents
- Ointments, creams that are used to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis
- Other products that contain such ingredients as sucralfate/hydrochloric acid and are used for the management of pain and relief of pain by adhering to the mucosal surface of the mouth and soothing oral lesions.

In reviewing the indications for use (IFU) for these various groups, we found them to be diverse to all be included in the same FRO category. However, the IFUs were consistent for similar types of products. Therefore, the FDA may want to consider additional categories for the many product types in this FRO category. We will address this in more detail in our oral comments at the meeting.

Products in FRO Category are Low to Moderate Risk in Terms of Safety and Effectiveness

Given the long history of the use of many of the products that are in the FRO category, the Coalition members believe that there is no need to re-establish their safety or efficacy. The benefits of their use outweighs their well understood risks and there are publications to support these conclusions.

In terms of safety, we have reviewed the MAUDE data from 2015- 2016 and found that there are no new significant risks identified; that is, that there were no reports that patients have developed any severe systemic infections or that there was an increase in serious adverse events associated with these products.

In addition, Coalition members who manufacture antimicrobial wound care products have indicated that in their monitoring over the years of product use there are no emerging issues related to of patients developing systemic infections or risks of bacterial resistance.

The Coalition appreciates the opportunity to provide our comments. If you need further information or have any questions, please do not hesitate to contact me.

Sincerely,

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