



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Ombudsman  
5600 Fishers Lane (HF-7)  
Room 14B-03  
Rockville, MD 20857

Food and Drug Administration  
Rockville MD 20857

December 6, 1999

Ms. Kathy Harris  
Director of Regulatory Affairs  
Johnson & Johnson Medical  
2500 E. Arbrook Blvd.  
Arlington, TX 76014

Re: Request for Designation  
[                    ]  
Our file: RFD 99.014

Dear Ms. Harris:

The Food and Drug Administration (FDA) has completed its evaluation of Johnson & Johnson Medical's (J & J) request for designation, received and filed on October 6, 1999.

The request covers [                    ]<sup>1</sup>, a wound dressing. The wound dressing consists of natural collagen and oxidized regenerated cellulose (ORC). (The request notes that natural collagen and ORC are each marketed as stand - alone medical devices.)

[                    ] According to the submission, the product will be indicated for [                    ]  
[                    ] in the management of diabetic [                    ] ulcers.

The request describes the complex progression of events resulting in wound healing. The request notes that tissue repair is a "controlled balance of repair processes, which lead to new tissue formation, and destructive processes, which are necessary to remove, damaged tissue."<sup>2</sup> J & J further states that chronic wounds, such as diabetic ulcers, are caused by an imbalance between tissue deposition stimulated by growth factors, and tissue destruction mediated by proteases (enzymes) in which the balance favors the destructive process.

<sup>1</sup> The request notes that this is the project code name.

<sup>2</sup> Request at page 4.

J & J postulates various mechanisms of action for [ ] including endogenous growth factor binding, release and protection; hemostasis of bleeding wounds; fibroblast chemotaxis and proliferation, and moist wound healing. However, J & J states that the primary mechanism of action is attributable to the reduction of the levels of destructive proteolytic enzymes in wound fluid through "a collagen and ORC matrix which acts as a scaffold that physically entraps proteases thereby mechanically modulating protease activity."<sup>3</sup>

J & J recommended that the Center for Devices and Radiological Health (CDRH) be assigned primary jurisdiction for the product's review and regulation under medical device authorities.

We have carefully considered the information in your request and discussed the issues raised with staff in the Center for Biologics Evaluation and Research (CBER) and CDRH. Based on our review, we are in substantial agreement with J & J's recommended assignment and classification of the product. CDRH is, therefore, assigned primary responsibility for the premarket review and regulation of the product.

The product will be reviewed under the medical device provisions of the Food, Drug and Cosmetic Act.<sup>4</sup> Our decision is based on our current understanding of the mechanisms of action of the product, including the product's role in physically reducing the activity of destructive enzymes in the wound. Moreover, classification of this product as a medical device is consistent with classification of other interactive wound dressings.

Prior to submitting its request for designation, J & J met with CDRH's Division of General & Restorative Devices (DGRD) to discuss submitting an investigational device exemption application for [ ] J & J should continue to work with DGRD, as it will be the primary review group. For further information contact Stephen Rhodes, Branch Chief, Plastics and Reconstructive Surgery Branch, Office of Device Evaluation, CDRH, 9200 Corporate Boulevard (HFZ-410), Rockville, MD 20850, or by telephone at 301-594-3090. Please include a copy of this letter in your next submission to CDRH.

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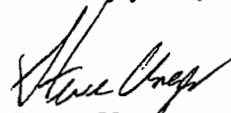
<sup>3</sup> Request at page 6.

<sup>4</sup> 21 U.S.C. § 360c et seq.

Johnson & Johnson Medical  
December 6, 1999  
Page 3

If you have any questions about this letter, please contact Tracey Forfa, of this office, at 301-827-3390.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Steven Unger". The signature is written in a cursive style with a large initial "S".

Steven Unger  
Acting Ombudsman