



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Combination Products
15800 Crabbs Branch Way (HFG-3)
Suite 200
Rockville, MD 20855

Food and Drug Administration
Rockville MD 20857

October 21, 2004

Steve Monroe, Ph.D.
Greystone Medical Group, Inc.
3251 Poplar Avenue, Ste. 150
Memphis, TN 38111

Re: Request for Designation
Epi-Max Impregnated Wound Dressing
Our file: RFD 2004.053
Dated: September 20, 2004
Received and Filed: September 21, 2004

Dear Dr. Monroe:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for the Epi-Max Impregnated Wound Dressing ("Epi-Max") that you submitted on behalf of Greystone Medical Group, Inc. ("Greystone") on September 20, 2004. The Office of Combination Products (OCP) filed the RFD on September 21, 2004. We have determined that the product is a combination product, and we have assigned it to the Center for Devices and Radiological Health (CDRH) as the lead agency center for premarket review and regulation based on our determination of the product's primary mode of action (PMOA).

Description of the Product

According to the RFD, the product is a sterile, non-adhesive, single-use, gauze dressing (2 x 3 in²) impregnated with the following components:

The product is intended as a non-adherent wound dressing where it would be indicated for use as a

According to the RFD, the product's primary intended purpose is to provide a protective physical barrier over the wound bed, which is accomplished by the gauze. Its secondary intended purpose, the RFD explains, is to provide a moist, reduced-adhesion environment conducive for wound healing, which is physically achieved by the

Finally, the RFD states that the product's tertiary intended purpose is to take advantage of the empirically observed effects of which are hypothesized to enhance the wound-healing process.

1 According to the RFD, the product is based on previously developed wound dressings

2 A change in the intended use of Epi-Max would require a separate jurisdictional determination.

Greystone recommends that Epi-Max be assigned to CDRH for premarket review and regulation. The company asserts that the product is substantially equivalent to other wound dressings, which have been classified as devices and regulated by CDRH.

Product Classification: Combination Product

Your product is comprised of both device and drug components. The classification of the gauze as a device is not in question. In addition, by providing a moist, reduced-adhesion environment, the [ ] also act physically and provide device functions. The [ ] the [ ] meet the definition of a drug.<sup>3</sup> Furthermore, the [ ] do not meet the definition of a device because they achieve their primary intended purposes of enhancing the wound healing process through chemical action within or on the body of man.<sup>4</sup>

We have determined that, because the product is comprised of both device and drug components, it is a combination product within the meaning of section 503(g) of the Federal Food, Drug, and Cosmetic Act (Act) and Title 21 of the Code of Federal Regulations (CFR) section 3.2(e)(1). In accordance with section 503(g)(1) of the Act and 21 CFR section 3.4, assignment of a lead Center to conduct the review of a combination product is based on the Agency's determination of the product's primary mode of action.

Assignment of Lead Center: CDRH

We have considered the information in the RFD, reviewed the pertinent provisions of the Intercenter Agreement (ICA) between CDRH and CDER, and discussed the issues with staff in both centers.

This product has three modes of action. Two actions of the product are the actions of the device components to provide a protective physical barrier over the wound bed, and to provide a moist environment conducive to wound healing. Another action of the product is the drug components' action to enhance the wound-healing process. We have determined that your product's primary mode of action is attributable to the device components' roles in providing a protective physical barrier over the wound bed, and in providing a moist environment conducive to wound healing. The drug components play a secondary role in enhancing the wound-healing process. Accordingly, we are assigning the product to CDRH for premarket review and regulation under the medical device provisions of the Act. Assignment of this product to CDRH is also consistent with the guidance provided by the ICA between CDRH and CDER (Sections VII.A.2 and VIII.A.5).

We have also made preliminary determinations about other regulatory requirements that will apply to your combination product. These are subject to further review by the agency. The combination product will be subject to the adverse event reporting requirements (21 CFR 803) applicable to devices, however certain drug reporting requirements (21 CFR 314) may apply. FDA recently published a draft guidance document "Current Good Manufacturing Practice for Combination Products," available at <http://www.fda.gov/oc/combo/default.htm>. Any clinical investigations of the combination product are subject to the investigational device exemption (IDE) requirements found in 21 CFR 812 and should be conducted in conformity with those regulations. CDRH will consult with CDER regarding the drug

<sup>3</sup> A drug is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or function of the body of man. Section 201(g) of the Act; 21 U.S.C. § 321(g).

<sup>4</sup> A device is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or function of the body of man. A device may not achieve its primary intended purposes through chemical action within or on the body of man. Section 201(h) of the Act; 21 U.S.C. § 321(h).

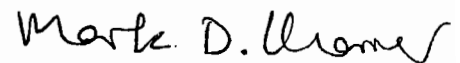
Steve Monroe, Ph.D.  
Greystone Medical Group, Inc.  
Page 3

component of your product. We encourage you to discuss with CDRH these and other regulatory requirements applicable to your combination product.

CDRH's Division of General, Restorative, and Neurological Devices (DGRND) will have lead responsibility for the combination product's premarket review and regulation. For further information about review requirements, please contact Mr. Stephen Rhodes, Chief, Plastic and Reconstructive Surgery Devices Branch, DGRND, at 301-594-3090, ext. 131. Please include a copy of this letter with your initial submission to CDRH.

You may request reconsideration of the classification or assignment of your product within 15 days of receipt of this letter. If you wish to request reconsideration, or for any other questions about this letter, please contact Leigh Hayes at (301) 427-1934. Finally, the Office of Combination Products is available to you as a resource for questions or issues that may arise throughout the development of your product. You may reach us at the above address or by email at [combination@fda.gov](mailto:combination@fda.gov).

Sincerely,



Mark D. Kramer  
Director  
Office of Combination Products

cc: Mr. Stephen Rhodes