DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Food and Drug Administration
Rockville MD 20857

January 17, 2007

Arthur B. Flick, MD
Medical Molecular Therapeutics, LLC
36 Lake Rabun Road
Lakemont, GA 30552

Re: Request for Designation
[ ] Skin and Wound Moisturizer Solution[1]
Our file: RFD060068
Dated: November 20, 2006
Received and Filed: November 20, 2006

Dear Dr. Flick:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for the [ ]Skin and Wound Moisturizer Solution that you submitted on behalf of Medical Molecular Therapeutics, LLC on November 20, 2006. The Office of Combination Products (OCP) received and filed the RFD on November 20, 2006. As explained below, we conclude that the [ ] Skin and Wound Moisturizer Solution 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 consists of [ ] and ionic silver, contained in a pump-spray bottle. [ ] The RFD further notes that the ionic silver "is there for antimicrobial protection of the aqueous wound cleanser solution." In a December 14, 2006 telephone call, Dr. Flick explained to Ms. Hayes of OCP that the [ ]

The RFD states that the product is "a [ ]skin and wound moisturizng solution intended for the external moisturizing of dermal wounds, inflamed skin and [ ][2] The RFD seeks two

[1] The RFD states that the product's name is "[ ]Skin and Wound Moisturizer Solution." However, in a phone call with Leigh Hayes on January 12, 2007, and in a subsequent email, Dr. Flick stated that he wished to amend the RFD to remove the word "[ ]' from the product's name. Consequently, our jurisdictional determination is for the product now named "[ ]Skin and Wound Moisturizing Solution."

separate indications for use, one indication for over-the-counter (OTC) use and one indication for professional prescription indications. For OTC indications, the RFD explains that the proposed labeling would state that is "[f]or minor [ ] abraded skin, irritated areas and minor wounds." The RFD states that the solution should be [

] For the prescription indication, the RFD explains that the proposed labeling would state that the product is "[f]or dermal lesions such as Stage I-IV pressure ulcers, stasis ulcers, foot ulcers, diabetic ulcers, post surgical wounds, first and second degree burns, cuts, abrasions, and skin irritations." [

]

You recommend that the [ ] Skin and Wound Moisturizer Solution be assigned to CDRH because you believe it has a device mode of action. You state that the product is intended to provide moisture to dermal wounds and inflamed skin.

Product Classification: Combination Product

We have determined that, because the product is comprised of drug (ionic silver)[3] and device (remaining ingredients comprising the aqueous solution and the pump-spray bottle) 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) and (2). 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 as well as the information you provided via telephone on December 14, 2006, and discussed the issues with staff in CDRH and the Center for Drug Evaluation and Research.

This product has two modes of action. One action of the product is the device components' action to provide moisture to dermal wounds and inflamed skin. Another action of the product is that of the drug component (ionic silver) to act as an antimicrobial agent. We have determined that the primary mode of action of the combination product is attributable to the device components' action to provide moisture to dermal wounds and inflamed skin.[4]

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[2] Our jurisdictional determination does not address the proposed use of your product for non-medical purposes, i.e., a[ ]

[3] The name of your product asserts that the ionic silver is acting as an antimicrobial agent, a drug mode of action. See 201(g) of the Act.

[4] We note that this jurisdictional determination applies only to the indication for [ ] Skin and Moisturizer Solution as presented in the RFD. Should you choose to make additional claims about the antimicrobial properties of the ionic silver in your product, a separate jurisdictional determination may be necessary.

Accordingly, we are assigning the product to CDRH for premarket review and regulation under the medical device provisions of the Act. Any clinical investigations of the combination product are subject to the investigational device exemption (IDE) requirements found at 21 CFR 812 and should be conducted in conformity with those regulations. For your information, FDA published a draft guidance document "Current Good Manufacturing Practice for Combination Products," available at http://www.fda.gov/oc/combination/default.htm, which provides information about the applicability of current good manufacturing practice regulations for combination products. We encourage you to discuss with CDRH these and other regulatory requirements applicable to your combination product.

CDRH's Plastic and Reconstructive Surgery Devices Branch will be responsible for the combination product's premarket review and regulation. For further information about review requirements and how to proceed with submitting an application to CDRH, please contact Mr. Stephen Rhodes, Chief, Plastic and Reconstructive Surgery Devices Branch, 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.

Sincerely,

Leigh Hayes
Product Assignment Officer
Office of Combination Products

cc: Stephen Rhodes