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
Silvaklenz [ ] Skin and Wound Cleanser Solution
Our file: RFD060067
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 Silvaklenz [ ] Skin and Wound Cleanser 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 Silvaklenz [ ] Skin and Wound Cleanser 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 [ ] cocamidopropyl betaine, [ ] and ionic silver, contained in a spray-pump bottle. The RFD explains that the cocamidopropyl betaine acts as a surfactant (soap). [ ] The RFD further notes that the ionic silver "is there for antimicrobial [ ]]

The RFD states that the product is "a buffered skin and wound cleansing solution intended for the external cleansing of dermal wounds, [ ] skin[1]." The RFD seeks two separate indications for use, one indication for over-the-counter (OTC) use and one indication for professional prescription indications. Proposed OTC indications include cleansing and removal of excessive oils, dirt

[1] [ ]

and debris from minor wounds, ulcerations and burns, abraded skin, and irritated areas. Proposed prescription indications include cleansing, moistening and irrigating [ ] dermal lesions; Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations. When the product is used on [ ] skin, the RFD states that the solution is sprayed [ ] onto the skin [ ] The skin is then gently rinsed with clear water [ ] If the product is used on an open wound or dermal lesion, the product is sprayed [ ] onto the wound. [ ]

You recommend that the Silvaklenz [ ] Skin and Wound Cleanser be assigned to CDRH because you believe it has a device mode of action. You state that the product is primarily intended to be a skin and wound cleanser to remove debris, necrotic tissue, and foreign particles from the skin and wound surface. You explain that the "mechanical action of the fluid moving across the skin or wound surface secondary to the spray mechanism on the dispensing bottle provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris." You further explain that the reduction in surface tension provided by the product's surfactant "assists with the mechanical debridement of debris, oils and foreign material from the skin or wound surface."

Product Classification: Combination Product

Under the Act, the term "drug" means articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function of the body of man or other animals.[4]

Under the Act, the term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[5]

We find that the cocamidopropyl betaine in your product meets the definition of a drug as set forth in the Act because its cleansing action depends on chemical action within or on the body of man in order to achieve its primary intended purposes.[6] We also find that the ionic silver[7]

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[2] [ ]

[4] Section 201(g) of the Act, 21 U.S.C. § 321(g)
[5] Section 201(h) of the Act, 21 U.S.C. § 321(h).
[6] You state that the surfactant is currently marketed in other OTC drug products under a tentative final monograph. You then suggest that the cocamidopropyl betaine is a device ingredient because it is the

component of your solution is a drug component for the use you indicate because[ ]the ionic silver is acting as an antimicrobial agent, a drug mode of action.

Therefore, we have determined that, because the product is comprised of drug (cocamidopropyl betaine and ionic silver) and device (the pump-spray and remaining ingredients comprising the aqueous solution) 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 PMOA.

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, the Center for Drug Evaluation and Research, and the Office of General Counsel.

This product has three modes of action. One action of the product is that of the device components (the pump-spray and the remaining ingredients of the aqueous solution) to mechanically remove debris, necrotic tissue and foreign particles from the skin and wound surface. A second mode of action is the action of the cocamidopropyl betaine (drug component) to reduce the surface tension and thereby assist with mechanical cleansing and debridement. A third mode of action is that of the other drug component (ionic silver) to act as an antimicrobial agent. We have determined that the PMOA of the combination product is attributable to the device components' action to remove debris, necrotic tissue, and foreign particles from the skin and wound surface through the mechanical process of spraying and washing the skin and/or wound.[8]

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

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subject of a TFM, and as you state, it is "removed from FDA consideration from possible future rulings." This is an incorrect statement in two respects. An ingredient that is subject to a TFM is considered to be a drug component. The agency, through its discretion, allows these ingredients to be marketed in over-the-counter products, assuming the products meet the qualifications set forth in the TFM. This allowance, however, does not change the classification of the ingredients as drugs that comprise the products. We note that cocamidopropyl betaine is not listed in the TFM you cite. Nevertheless, we find that the surfactant meets the definition of a drug for the intended use presented in this RFD because it depends on chemical action within or on the body of man in order to achieve its primary intended purposes.

[7] 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.

[8] We note that this jurisdictional determination applies only to the indication for Silvaklenz [ ] Skin and Cleanser 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.

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 me 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.

Sincerely,

Leigh Hayes

Leigh Hayes
Product Assignment Officer
Office of Combination Products

cc: Stephen Rhodes