



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

Food and Drug Administration
Rockville MD 20857

July 24, 2007

Greg J. Archambeau
Vice President of Product Development
Revalesio Corporation
5102 20th Street East
Building 100
Tacoma, WA 98424

Re: Request for Designation
REVERA™ Wound Care
Our File Number: RFD070026
Received: May 25, 2007
Filed: May 25, 2007

Dear Mr. Archambeau:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for REVERA™ Wound Care, dated May 24, 2007. The Office of Combination Products (OCP) received and filed the RFD on May 25, 2007. We have determined that REVERA™ Wound Care 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, REVERA™ Wound Care is a solution comprised of 0.9% USP Sodium Chloride for Irrigation and [REDACTED]. The RFD states that the product is indicated for moistening and debriding acute and chronic dermal lesions, such as Stage I – IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions and minor irritations of the skin, in addition to moistening and lubricating absorbent wound dressings for traumatic wounds, cuts, abrasions and minor burns.

According to the RFD, REVERA™ Wound Care has two modes of action. The first mode of action is that of the fluid moving across the wound to mechanically cleanse, debride, and remove foreign material from a wound.¹ The second mode of action is the [REDACTED] action to inhibit the growth of pseudomonas if used on a wound dressing.²

The RFD recommends that REVERA™ Wound Care be classified as a device and assigned to CDRH. Alternatively, the RFD states that if REVERA™ Wound Care is classified as a device/drug combination product, it should be reviewed by CDRH because the mechanical action of the solution provides the most important therapeutic action and is consistent with the labeling and intended use of the product.

Product Classification: Combination Product

Under the Act, a drug is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or an article intended to affect the structure or any function of the body of man or other animals.³

Under the Act, a device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, 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.⁴

We find that the sodium chloride component of REVERA™ Wound Care meets the definition of a device because it is intended to mechanically cleanse, debride, remove

¹ Although not expressly identified by you as a "mode of action," we note that the RFD also describes moistening and lubricating absorbent wound dressings as a proposed use or indication for the REVERA™ Wound Care product.

² In a telephone conversation and in a subsequent email sent to Ms. Leigh Hayes on July 23, 2007, Mr. Greg Archambeau explained that the studies referenced in the RFD concern the growth of pseudomonas on a wound dressing with agar and in broth. Mr. Archambeau stated that the [REDACTED] in this product is not intended to inhibit the growth of pseudomonas directly on a wound.

³ Section 201(g) of the Act; 21 U.S.C. § 321(g).

⁴ Section 201(h) of the Act, 21 U.S.C. § 321(h).

foreign material, and moisten the wound and to moisten and lubricate a wound dressing. We find that the [REDACTED] meets the definition of a drug because it is intended to act as an antimicrobial agent, a drug mode of action.

We have determined that because REVERA™ Wound Care is comprised of a device component and a drug component, it is a combination product within the meaning of section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(g)), and 21 CFR 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 PMOA.

Assignment of Lead Center: CDRH

We have considered the information in the RFD and the information you provided via telephone and email on July 23, 2007, and discussed the issues with staff in CDRH, the Center for Drug Evaluation and Research (CDER), and the Office of General Counsel.

This product has two modes of action. One action of the product is that of the device component (sodium chloride solution) to mechanically cleanse, debride, remove foreign material, and moisten a wound and to moisten and lubricate a wound dressing. A second mode of action is the action of the drug component ([REDACTED]) to act as an antimicrobial agent. We have determined that the PMOA of the combination product is attributable to the device component's action to mechanically cleanse, debride, remove foreign material, and moisten a wound and to moisten and lubricate a wound dressing.⁵

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/combinat/default.htm>, which provides information about FDA's draft policies concerning 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.

⁵ We note that this jurisdictional determination applies only to the intended therapeutic effects or actions for REVERA™ Wound Care as described in the RFD and in subsequent, related communications with this office. Should you choose to make any claims regarding additional therapeutic effects or actions, for example, concerning antimicrobial effects of the [REDACTED] directly on the wound itself, a separate jurisdictional determination would be necessary.

Revalerio Corporation
July 24, 2007
Page 4

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 Dr. David Krause, Acting Chief, Plastic and Reconstructive Surgery Devices Branch, at 240-276-3621. 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,

A handwritten signature in black ink that reads "Leigh Hayes". The signature is written in a cursive, flowing style.

Leigh Hayes
Product Assignment Officer

cc: Victoria Lutwak