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

May 9, 2005

Sophie Fortin
Laboratoires Urgo
42 Rue de Longvic
21300 Chenove, France

Re: Request for Designation
Urgotul® [redacted]
Our file: RFD 2005.009
Dated: Undated
Received and Filed: March 23, 2005
Amended: April 25 and May 4, 2005

Dear Ms. Fortin:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for Urgotul® [redacted] Urgotul), submitted by Laboratoires Urgo, on March 23, 2005. The Office of Combination Products (OCP) filed the RFD on March 23, 2005. 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, as well as subsequent information provided by telephone on April 25 and by email on May 4, 2005, Urgotul is a non-adhesive, non-occlusive, antimicrobial hydrocolloid wound contact dressing, composed of a flexible polyester mesh which is impregnated with a matrix of hydrocolloid particles. The matrix is comprised of [redacted] carboxymethyl cellulose [redacted] cohesive polymers [redacted] and silver sulfadiazine [redacted] The RFD explains that on contact with wound exudates, Urgotul forms a gel that creates a moist wound-healing environment supportive of the healing process.

The product is intended to act as an effective barrier to bacterial penetration to the wound, while the silver sulfadiazine component prevents bacterial colonization on the dressing. Urgotul is indicated for use in the management of second-degree (partial thickness) burns. The dressing would be applied directly to the wound, and changed every 24-48 hours, depending on healing progress. Duration of treatment is determined by a physician and depends on wound type and conditions.

You recommend that Urgotul be assigned to CDRH for premarket review and regulation. You base this recommendation on your assertion that the product's PMOA is to act as a barrier to bacterial penetration to the wound and to provide a moist wound healing environment, while its secondary mode of action is to prevent bacterial colonization on the dressing.

[redacted]

Product Classification: Combination Product

We have determined that, because the product is comprised of both device (wound dressing) and drug (silver sulfadiazine) 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).

Therefore, in accordance with 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

One action of the product is to act as an effective barrier to bacterial penetration to the wound, and to provide a moist wound healing environment. Another action of the product is to prevent bacterial colonization on the dressing.

Based on the intended use as set forth in the RFD, we have determined that the product's primary mode of action is attributable to the device component's function of providing an effective barrier to bacterial penetration and a moist wound healing environment, while the drug component plays a secondary role in preventing bacterial colonization on the dressing. Accordingly, based on the data currently available, 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. FDA recently published a draft guidance document "Current Good Manufacturing Practice for Combination Products, available at http://www.fda.gov/oc/combination/default.htm, that provides information about the applicability of current good manufacturing practice regulations for combination products, and we expect to publish guidance about the applicability of adverse event reporting regulations for combination products. We encourage you to discuss with CDRH these and other regulatory requirements applicable to your combination product.

[redacted] If FDA determines upon further review that the product acts differently than you have described in the RFD, then a separate jurisdictional determination may be necessary.

CDRH's Division of General, Restorative, and Neurological Devices (DGRND) will have lead responsibility for the combination product's premarket review and regulation. Due to the safety and effectiveness questions presented by the drug component of your combination product, CDRH will collaborate with the Center for Drug Evaluation and Research on the review of the silver sulfadiazine component of your product.[2] 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.

[2] In a collaboration, reviewers in each Center have primary review responsibility, generally for a defined portion of a submission. Regulatory and scientific decisions will be made by the management of each Center for that portion of the review assigned to it, including the decision to approve or not approve the product. See Manual of Standard Operating Procedures and Policies, General Information - Review Intercenter Consultative/Collaborative Review Process available at http://fda.gov/oc/combination/intercentersop.html.

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

Cc: Stephen Rhodes