DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Food and Drug Administration
Rockville MD 20857

March 30, 2005

Patrick D. McGrath, Ph.D.
1471 Greystone Drive
Gurnee, IL 60031

Re: Request for Designation
Sucralfate HCl Topical Paste
Our file: RFD 2005.003
Dated: February 9, 2005
Received and Filed: February 11, 2005
Amended: March 21, 24, and 29, 2005

Dear Dr. McGrath:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) you submitted for Sucralfate HCl Topical Paste™ on February 9, 2005. The Office of Combination Products (OCP) filed the RFD on February 11, 2005. We received additional information on March 21, 24, and 29, 2005, including a copy of the premarket notification (K043587) you submitted to the Center for Devices and Radiological Health (CDRH) covering Sucralfate HCl Topical Paste™. As explained below, we conclude that Sucralfate HCl Topical Paste™ is a device that will be reviewed and regulated by CDRH under the device provisions of the Federal, Food, Drug, and Cosmetic Act (the act).

Description of the Product

According to the RFD, Sucralfate HCl Topical Paste™ is an amorphous hydrogel paste formed by mixing sucralfate with hydrochloric acid prior to use. The RFD states that the paste is intended to relieve pain[ ] by physical coverage of oral[ ]wounds.

According to 510(k) K043587, the product is comprised of sucralfate [ ] [ ] of Sucralfate HCl Topical Paste™ to be prepared at the point of care. [ ] [ ] [ ]

The RFD states that sucralfate is currently available as Carafate®, a 1 gram tablet marketed by Axcan Pharma, intended for duodenal ulcer healing, and as a generic drug marketed by Teva Pharmaceuticals. According to the information submitted on

March 24 and 29, 2005, the Sucralfate HCl Topical Paste™ [redacted]

Alternatively, you may make Sucralfate HCl Topical Paste™ [redacted]

As explained in the RFD, sucralfate is insoluble in water and common organic solvents, but is soluble in strong aqueous acids, such as stomach acid or hydrochloric acid. According to the RFD, once a sucralfate tablet taken orally begins to be dissolved by stomach acid, but prior to complete dissolution, the sucralfate and the stomach acid react within the gastrointestinal tract to form an amorphous aqueous paste. The RFD states that this internally formed paste adheres to and covers gastrointestinal wounds, such as duodenal ulcers.

In contrast to sucralfate tablets taken orally, the RFD states that with Sucralfate HCl Topical Paste™, the sucralfate – HCl reaction that forms the paste will take place in a jar prior to dosing. The RFD states that Sucralfate HCl Topical Paste™ is applied directly to accessible wounds in a form that does not require any additional metabolic transformation in order to serve as a wound covering.

The RFD recommends that Sucralfate HCl Topical Paste™ be classified as a device that will be reviewed and regulated by CDRH under the device provisions of the act.

Product Classification: Device

We have considered the information in the RFD and discussed the issues with staff in CDRH and the Center for Drug Evaluation and Research.

We conclude that Sucralfate HCl Topical Paste™ achieves its primary intended purposes of relieving pain [redacted] of oral [redacted] wounds by physical coverage of the wound. Unlike sucralfate tablets taken orally, the reaction between sucralfate and an acid that creates the Sucralfate HCl Topical Paste™ does not occur within or on the body of man. Therefore, we conclude that Sucralfate Topical HCl Paste™ meets the definition of a device in that it is intended for use in the cure,

mitigation, treatment, or prevention of disease in man, and it does not achieve its primary intended purposes through chemical or metabolic action within or on the body of man.[1] Accordingly, we conclude that Sucralfate HCl Topical Paste™ is appropriately regulated by CDRH under the device provisions of the Act.[2]

CDRH's Division of General, Restorative, and Neurological Devices, Plastic and Reconstructive Surgery Branch will be responsible for the product's premarket review and regulation. CDRH will consult with CDER as appropriate in its review of Sucralfate HCl Topical Paste. CDRH will review the product under the medical device provisions of the act. Any clinical investigation must be conducted in accordance with the Investigational Device Exemption (IDE) regulations (21 CFR Part 812).

We understand that CDRH's review of 510(k) K043587 has been put on hold pending resolution of this RFD. The Office of Combination Products will send a copy of this letter to CDRH to notifying it of the determination that Sucralfate HCl Topical Paste™ is a device. At that time, we will ask CDRH to take 510(k) K043587 off hold, and proceed with its review. If you have any questions about the continuing review of your 510(k), please contact Stephen Rhodes, Chief, Plastic & Reconstructive Surgery Devices Branch, 301-594-3090 x131.

You may request reconsideration of the classification 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.

Sincerely,

Suzanne O'Shea
Product Classification Officer

---

[1] Section 201(h) of the Act; 21 U.S.C. § 321(h).
[2] This conclusion relies on the sponsor's statement that if