



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner  
5600 Fishers Lane  
Room 14-105, HF-7  
Rockville, MD 20857

Food and Drug Administration  
Rockville MD 20857

May 30, 1997

Handwritten scribbles and marks, possibly initials or a signature, located above the subject line.

Re: Request for Designation  
Sorbastace  
Our file: RFD 97.005

Dear [ ]

This letter responds to your request for designation, dated March 31, 1997, submitted on behalf of Hemostace, L.L.C., covering the product Sorbastace. We have completed our review of your request for designation. The Center for Devices and Radiological Health (CDRH) will be assigned primary jurisdiction for the premarket review of this product, and review under the device authorities of the Federal Food, Drug, and Cosmetic Act (the Act) is required.

Sorbastace consists of fine granules of [ ] Hemostace intends to package the granules in packets for convenient sprinkling into laceration wounds. The product is intended to be applied to fresh traumatic lacerations to absorb body fluid, and stop minor bleeding. After exudation and bleeding have stopped, the product is irrigated from the wound and a protective dressing is applied. According to Hemostace, the relatively large surface area of the granules fosters coagulation. In addition, according to Hemostace, the [ ] granules absorb fluid into their interior spaces; the absorbed fluid dissolves the [ ] which is then released from the [ ] granules to act as an astringent within the wound site. Hemostace recommended that the CDRH be given primary jurisdiction for the premarket review and regulation of the product under the device authorities of the Act.


After considering the information Hemostace submitted, and conferring with the two affected centers (CDRH and the Center for Drug Evaluation and Research (CDER)), I am in agreement with your recommendation. Therefore, I am designating CDRH as the agency component with primary jurisdiction for the review of this product. The product will be regulated under the device provisions of the Act, 21 U.S.C. § 360c et seq.

Hemostace, L.L.C.  
May 30, 1997  
Page 2

Hemostace submitted this request for designation in response to our letter, dated March 17, 1997, informing Hemostace that a jurisdictional issue was presented by its 510(k) premarket notification covering Sorbastace, submitted to CDRH on December 17, 1996. Pursuant to 21 C.F.R. § 3.10 of the product jurisdiction regulations, review of the 510(k) premarket notification was suspended pending resolution of the jurisdictional issue. CDRH's Plastic and Reconstructive Surgery Branch, Division of General and Restorative Devices is now continuing its review of the 510(k) in consultation with CDER, as necessary. CDRH will issue its evaluation of Hemostace's 510(k) in the near future.

If you have any questions concerning this matter, please contact Suzanne O'Shea, of this office, at 301-827-3390.

Sincerely yours,



Amanda Bryce Norton  
Chief Mediator and Ombudsman