File

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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

September 27, 1996

Ross Erickson
Vice President
Regulatory Affairs and Clinical Research
Cohesion Corporation
2500 Faber Place
Palo Alto, CA 94303

Re: Request for Designation
[ ] Hemostatic Agent [ ]
Our File: RFD 96-14

Dear Mr. Erickson:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on June 26, 1996. Information in the request was supplemented with information provided by the company in a meeting with FDA staff on September 17, 1996. By agreement, the deadline for a jurisdictional determination was extended to September 27, 1996.

[ ] when provided to the end-user (e.g., the operating room surgeon), consists of a prefilled syringe containing a [ ] mixture of [ ] bovine collagen, bovine thrombin, and calcium chloride. The product is intended for use with a patient's own plasma, which must be collected into a second syringe at the time of surgery. The two syringes are connected to a mixer/applicator (also supplied with the product). The applicator mixes the contents from the two syringes during the spray application process. The mixture [ ] [ ]. According to the request, [ ] is intended for use in surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

The request for designation argued that [ ] is a combination product whose primary mode of action is that of a device. Cohesion recommended that primary regulatory responsibility for [ ] be assigned to the Center for Devices and Radiological Health (CDRH).

After considering the information in the request, and consulting with appropriate officials in CDRH and the Center for Biologics Evaluation and Review (CBER), I am designating CDRH as the agency component with primary jurisdiction for the premarket review and regulation of the combination product.

[ ] will be regulated under the medical devices provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360c et seq.). Any clinical investigations of the product should be conducted in accordance with the investigational device exemption requirements in 21 C.F.R. Part 812.

The Plastic and Reconstructive Surgery Branch in the Division of General and Restorative Devices (DGRD), Office of Device Evaluation will be the primary review office. The Division will conduct its review in collaboration with review team members from CBER. The collaboration will be designed to ensure that the standards for the clinical assessment of [ ] and related products are consistently applied. For further information, contact Mr. Stephen Rhodes, M.S., Chief, Plastic and Reconstructive Surgery Branch, DGRD (HFZ-410), 9200 Corporate Boulevard, Rockville, MD 20850. He can be reached at 301-594-2036.

Please include a copy of this letter in your initial submission to CDRH.

If this office can be of any further assistance, please call me at 301-827-3390.

Sincerely yours,

Steven H. Unger
Deputy, Office of the Chief
Mediator and Ombudsman

cc: Mr. Rhodes