RFD 93-04

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
301-443-1306

June 7, 1993

Mr. Dennis M. DeCola
Director, Regulatory Affairs
Therakos
210 Brandywine Parkway
West Chester, PA 19380

Re: Request for Designation for Photopheresis System
Our File: RFD 93-04

Dear Mr. DeCola:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on April 7, 1993.

Photophoresis therapy consists of devices that emit long-wave ultraviolet light to photoactivate formulations of 8-methoxypsoralen (8-MOP). The 8-MOP enters the cell nuclei and [redacted] Photophoresis is indicated for the palliative treatment [redacted] of cutaneous T-cell lymphoma.

On October 28, 1992, we confirmed the prior guidance of January 31, 1992, regarding the premarket review and regulation of photophoresis therapy. We advised that the Center for Drug Evaluation and Research (CDER) would retain primary jurisdiction for the premarket review and evaluation of new indications and new formulations of 8-MOP used in conjunction with the currently-approved photophoresis device. The Center for Devices and Radiological Health (CDRH) would have primary jurisdiction for the review of the photophoresis device used with approved 8-MOP formulations for approved indications.

The current request for designation involves a photophoresis system where the 8-MOP is delivered extracorporeally, rather than being ingested by the patient. This necessitates a new formulation of the 8-MOP, from [redacted] to a liquid form, as well as modifications to the photophoresis device itself. You

recommend that CDRH be given primary jurisdiction for this modified photophoresis system.

After conferring with the two affected Centers, I am affirming the earlier jurisdiction determination. CDER will be the agency component with primary jurisdiction for the premarket review and regulation of the new formulation of 8-MOP under the new drug provisions of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. § 355; 21 C.F.R. Parts 312 and 314.) CDRH will have primary jurisdiction for the review and regulation of the modified photopheresis device itself, as it is used with 8-MOP delivered extracorporeally. CDRH will review and regulate the photopheresis device under the device authorities of the act (21 U.S.C. § 360e et seq., 21 C.F.R. Parts 812 and 814).

Any clinical trials must be conducted in accordance with the Investigational New Drug (IND) regulations (21 C.F.R. Part 312). CDER's Division of Oncology and Pulmonary Drug Products (HFD-150) will be the primary reviewing division, and will consult closely with CDRH on the IND. For further information, please contact Kathleen Downs, Consumer Safety Officer, at 301-295-9135. Please submit a copy of this designation letter with your initial submission to CDER. Because of the complexities of this matter, I recommend that you request a joint meeting with CDRH and CDER staffs before beginning additional clinical trials.

Please note that the Prescription Drug User Fee Act of 1992 applies to certain new drug applications filed after September 1, 1992. For additional information about user fees, contact FDA's Office of Small Business, Scientific and Trade Affairs at 301-443-6776.

You may request reconsideration of the designation decision within 15 days of receipt of this letter. See 21 C.F.R. § 3.8(c). If you have any questions concerning this matter, please do not hesitate to telephone me or Ms. Suzanne O'Shea of this office at 301-443-1306.

Sincerely,

Amanda B. Pedersen