NDA 20-969

THERAKOS, Inc.
437 Creamery Way
Exton, PA 19341

Attention: Peggy Schwartz
Manager, Regulatory Affairs

Dear Ms. Schwartz:

Please refer to your new drug application (NDA) dated February 20, 1998, received February 25, 1998, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for UVADEX® (methoxsalen) Sterile Solution, 20 mcg/mL.

We acknowledge receipt of your submissions dated March 19 and 26; April 16, 17, and 29; May 8 and 11; June 10; August 21; September 10; and November 16, 1998; and January 6, 1999. The user fee goal date for this application is February 25, 1999.

This new drug application provides for the use of UVADEX® (methoxsalen) Sterile Solution with the UVAR® Photopheresis System in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-969." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Debra Catterson, Project Manager, at (301) 827-1544.

Sincerely,

Robert Justice, M.D.
Acting Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure