

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 20-969**

**CORRESPONDENCE**

**THERAKOS**  
a Johnson & Johnson company

DUPLICATE

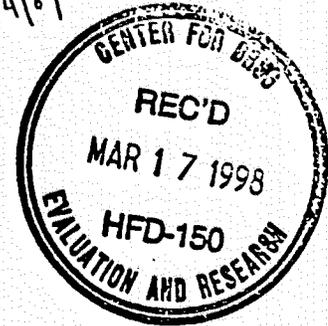
NEW CORRESP

NC

NOTED  
NAI  
D Catterson  
4/8/98

March 16, 1998

Ms. Debra Catterson, Project Manager  
Division of Oncologic Drug Products (HFD-150)  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Document Control Room 2095, Woodmont Office Complex 2  
1451 Rockville Pike  
Rockville, MD 20857



RE: UVAR<sup>®</sup> Photopheresis/UVADEX<sup>®</sup> liquid methoxsalen  
NDA 20,969 New Correspondence

Dear Debbie,

THERAKOS is hereby submitting a copy of the Debarment Statement that was inadvertently omitted from our New Drug Application for UVADEX<sup>®</sup> liquid methoxsalen, NDA 20, 969.

We understand that all information contained herein, unless otherwise made public by THERAKOS, is **CONFIDENTIAL**.

Please call me at (610) 280-1021 if there are any questions or comments regarding this submission.

Sincerely,

Peggy Schwartz  
Manager, Regulatory Affairs

Enclosures

# THERAKOS ORIGINAL

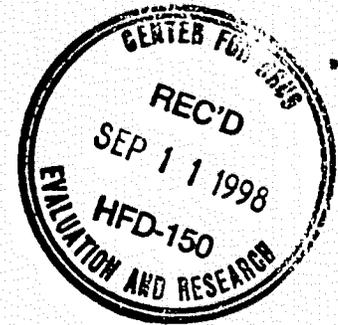
a Johnson & Johnson company

September 10, 1998

Dr. Robert Justice, Acting Director  
Division of Oncologic Drug Products (HFD-150)  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Document Control Room 2095, Woodmont Office Complex 2  
1451 Rockville Pike  
Rockville, MD 20857

ORIG AMENDMENT

SU



RE: UVAR® Photopheresis/UVADEx® liquid methoxsalen  
NDA 20,969 - Safety Update Report

Dear Dr. Justice,

Reference is made to NDA 20,969, submitted on February 25, 1998. In accordance with 314.50 THERAKOS is hereby submitting the following information regarding the required safety update report:

As of the submission date, February 25, 1998, all clinical studies were completed. The treatment period for CTCL 3 was 4/20/93 to 7/11/96. Therefore, there is no additional safety information to be reported for NDA 20,969.

A form 356h is attached.

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Please call me at (610) 280-1021 if there are any questions or comments regarding this submission.

Sincerely,

Peggy Schwartz  
Manager, Regulatory Affairs