DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 13 2006

Re: Uvadex
Docket No. 99E-5117

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,999,375 filed by Therakos, Inc. under 35 U.S.C. § 156. The human drug product claimed by the patent is Uvadex (methoxysalen), which was assigned new drug application (NDA) No. 20-969.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that Uvadex does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in *Glaxo Operations UK Ltd. v. Quigg*, 706 F. Supp. 1224 (E.D. Va. 1989), *aff'd*, 894 F. 2d 392 (Fed. Cir. 1990). Methoxysalen, the active ingredient of Uvadex, was previously approved under section 505 of the Federal Food, Drug, and Cosmetic Act on June 8, 1982.

The NDA 20-969 was approved on February 25, 1999, which makes the submission of the patent term extension application on April 16, 1999, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: John W. Wallen, III
Johnson & Johnson, Corporate
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

Todd Volyn
Johnson & Johnson, Corporate
One Johnson & Johnson Plaza (WH4231)
New Brunswick, NJ 08933-7003