



Food and Drug Administration
Rockville MD 20857

AUG 31 2004

Re: Visudyne
Docket No.: 01E-0032

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

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,095,030, filed by University of British Columbia, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Visudyne, the human drug product claimed by the patent.

The total length of the regulatory review period for Visudyne is 3,194 days. Of this time, 2,953 days occurred during the testing phase and 241 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 17, 1991.

The applicant claims June 21, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 17, 1991, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: August 16, 1999.

The applicant claims August 24, 1999, as the date the new drug application (NDA) for Visudyne (NDA 21-119) was initially submitted. However, FDA records indicate that NDA 21-119 was submitted on August 16, 1999.

3. The date the application was approved: April 12, 2000.

FDA has verified the applicant's claim that NDA 21-119 was approved on April 12, 2000.

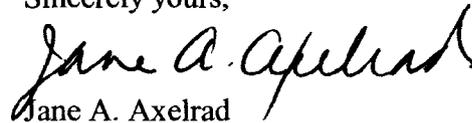
01E-0032

LET 3

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

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

Sincerely yours,



Jane A. Axelrad

Associate Director for Policy

Center for Drug Evaluation and Research

cc: Kate H. Murashige, Esq.
Morrison & Foerster, LLP
12636 High Bluff Drive, Suite 300
San Diego, CA 92130