



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-119/S-013

QLT, Inc.
c/o QLT USA, Inc.
Attention: Elyse Wolff, Regulatory Affairs
2759 Midpoint Drive
Fort Collins, CO 80525

Dr. Ms. Wolff:

Please refer to your supplemental new drug application dated June 29, 2004, received July 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visudyne (verteporfin for injection), 15 mg.

We acknowledge receipt of your submissions dated June 29, 2006, August 17, 2007, February 25 and March 14, 2008. Your submission of June 29, 2006, constituted a complete response to our April 29, 2005, action letter.

This supplemental application proposed to make changes to the package insert.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 14, 2008.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lori M. Gorski, Regulatory Project Manager, at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology
Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Wiley Chambers
6/30/2008 10:32:27 AM