DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-119/S-012

QLT Inc.
Attention: Lawrence Taylor, Manager Regulatory Affairs
c/o Jonathan S. Kahan
Hogan and Hartson
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Dear Mr. Taylor:

Please refer to your supplemental new drug application dated February 18, 2004, received February 19, 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 submission dated September 24, 2004, which constituted a complete response to our August 16, 2004, action letter.

This supplemental new drug application, submitted as "Changes Being Effected" proposes clinical changes to the labeling. However, as we notified you in our February 23, 2004, acknowledgement letter to this application, an approved supplement is required for changes such as these prior to distributing drug product. Therefore, this supplement was reviewed as a prior approval supplement.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the labeling text for package insert submitted September 24, 2004. The text for the approved package insert is enclosed. Approval by FDA of the FPL submission is not required before the labeling is used.

For future supplements, the electronic labeling rule that was published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). These guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format with proposed revisions clearly indicated. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send 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-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
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, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Wiley Chambers

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