DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-119
PMA P990048
PMA P990049

APR 12 2000

QLT PhotoTherapeutics
Attention: David Mitchell, Director Regulatory Affairs
c/o Jonathan S. Kahan
Hogan and Hartson
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Dear Mr. Mitchell:

Please refer to your new drug application (NDA) and pre-market applications (PMA) dated August 14, 1999, submitted under sections 505(b) and 515 of the Federal Food, Drug, and Cosmetic Act for Visudyne (verteporfin for injection), 15 mg, for the Coherent Opal Photoactivator Laser Console and LaserLink Adapter (P990049), and for the Zeiss VISULAS 690s laser and VISULINK PDT adapter (P990048).

We acknowledge receipt of your submissions dated October 18, November 2 and 15, and December 10, 1999, and January 21, 2000, to PMA P990048; December 3 and 10, 1999, to PMA P990049; and February 1, 8, and 18, March 2, 3, 6, 7, 24 (two), 30, and 31, and April 3 (two), 5, and 7, 2000 to NDA 21-119. Your submission of February 18, 2000, constituted a complete response to our February 11, 2000, action letter.

These applications provide for the treatment of age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularization.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the combination is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the applications are approved effective on the date of this letter.

The sale, distribution, and use of these devices are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the devices are further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

The Center for Devices and Radiological Health (CDRH) will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act.

The final printed labeling (FPL) for Visudyne must be consistent with the draft labeling submitted April 7, 2000. Marketing the product with FPL that is not consistent with the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-119." Approval of this submission by FDA is not required before the labeling is used.

You are reminded that, as soon as possible and before commercial distribution of your devices, you must submit amendments to these PMA submissions with copies of all approved labeling in final printed form.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not in final print. Please send one copy to the Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81 for the drug product. Failure to comply with the conditions of approval for the devices invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

If you have any questions, call Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

Robert J DeLap 4/12/00

Robert DeLap, M.D., Ph.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research