

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-119 /S-003

APPROVABLE LETTER



NDA 21-119/S-003

QLT Inc.
Attention: David Mitchell, Sr. Manager 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 supplemental new drug application dated October 12, 2001, received October 15, 2001, 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 November 2, 2001.

This "Changes Being Effected" supplemental new drug application proposes changes to the package insert.

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit draft labeling with the following addition to the Indications and Usage section:

[]

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

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 final print. Please submit 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, Maryland 20857

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application.

Under 21 CFR 314.102(d) of the new drug regulations, you may request an informal meeting or telephone conference with this division to discuss what further steps need to be taken before the application may be approved.

This product may be considered to be misbranded under the Federal Food, Drug and Cosmetic Act if it is marketed with the changes proposed in this supplement prior to approval of this application.

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

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/s/

Wiley Chambers
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Washington, D.C. 20004-1109

Dear Mr. Mitchell:

Please refer to your supplemental new drug application dated October 12, 2001, received October 15, 2001, 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 January 30, and 31, and February 28, 2002. The January 30, 2002 submission constituted a complete response to our November 6, 2001, action letter.

This "Changes Being Effected" supplemental new drug application proposes changes to the package insert.

We have completed the review of this application, as amended, and it is approvable. The changes submitted to the Division in the January 30, 2002, submission are unacceptable. Specifically, the suggested change to the Indication and Usage section does not adequately state the limitation of usefulness of Visudyne. The suggested change to the Warning section reinforces an unapproved indication. The suggested change to the Adverse Reactions section is not consistent with the data.

The Division reaffirms the previous decision that before this application may be approved it will be necessary for you to submit draft labeling with the following statement added to the Indications and Usage section:

[]

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

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/s/

Wiley Chambers
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