

NDA 20-451/S-003

DEC 22 1998

QLT Phototherapeutics, Inc.
Attention: Mr. Jonathan Kahan
Hogan & Hartson
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Dear Mr. Kahan:

Please refer to your supplemental new drug application dated March 23, 1998, received March 25, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Photofrin (porfimer sodium) for Injection, 75 mg vial for use in photodynamic therapy with the following devices:

1. The OPTIGUIDE Cylindrical Fiber Optic (DCYL Diffuser Series); and
2. the Coherent Lambda Plus PDL1 and PDL2 Photodynamic Lasers; or
3. the Laserscope Series 600 Dye Laser Modules (operating at 630 +/-3nm) and Series 800 KTP/532 and KTP/YAG (operating at 532nm) Surgical Lasers.

We acknowledge receipt of your submissions dated September 14 and October 5, 1998.

This supplemental new drug application provides for Photofrin for use in photodynamic therapy (PDT) for reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial nonsmall cell lung cancer (NSCLC).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to 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

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similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-451/S-003." Approval of this submission by FDA is not required before the labeling is used.

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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Paul Zimmerman, Project Manager, at (301) 594-5775.

Sincerely yours,

Robert L. Justice, M.D.
Acting Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure