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Application Number 020451/S-002

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-451/S-002

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

JAN - 9 1998

Dear Mr. Kahan:

Please refer to your supplemental new drug application dated February 7, 1997, received February 10, 1997, 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 Fiber Optic (DCYL Cylindrical Diffuser Series); and

2. the Coherent Lambda Plus PDL1 and PDL2 Photodynamic Lasers; or

3. the Laserscope Series 600 Dye Modules (Models 630 and 630XP) and the Series 800 KTP/532 or KTP/YAG Surgical Lasers.

We acknowledge receipt of your submissions dated March 27, April 21 and 22, June 10, September 3 and 15, November 17, and December 12, 16 and 20, 1997. The User Fee goal date for this application is February 10, 1998.

The supplemental application provides for Photofrin for use in photodynamic therapy for treatment of microinvasive endobronchial nonsmall cell lung cancer in patients for whom surgery and radiotherapy are not indicated.

We have completed the review of this supplemental application, including the submitted draft labeling, 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 draft labeling in the submission dated December 20, 1997. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on December 20, 1997.

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 "FINAL PRINTED LABELING" for approved supplemental NDA 20-451/S-002. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material 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 material and the package insert directly to:

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

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be 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 20852-9787

While this approval is limited to the microinvasive nonsmall cell lung cancer indication as noted above, the initial supplemental application, prior to amendment,

(b)4 - Confidential Business

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, please contact Paul Zimmerman, Project Manager, at (301) 594-5775.

Sincerely yours,

/S/

Robert J. DeLap, M.D., Ph.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research