CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-119 /S-004

ADMINISTRATIVE AND CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-119/S-004

PRIOR APPROVAL SUPPLEMENT

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

Dear Dr. Stokl:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Product: Visudyne (verteporfin for injection), 15 mg.

NDA Number: 21-119

Supplement Number: S-004

Date of Supplement: January 31, 2002

Date of Receipt: February 1, 2002

This supplement proposes the addition of an alternate manufacturing site for the drug product.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on April 1, 2002, in accordance with 21 CFR 314.101(a).

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
9201 Corporate Boulevard
Rockville, Maryland 20850-3202

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

Sincerely,

{See appended electronic signature page}

Carmen DeBellas, R.Ph.
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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

/s/

Lori Gorski
2/12/02 09:56:31 AM
Lori Gorski has signed for Carmen DeBellas

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FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 21119/004
Priority: 1P
Org Code: 550
Stamp: 01-FEB-2002 Regulatory Due: 01-JUN-2002
Action Goal:
District Goal: 27-APR-2002
Applicant: QLT
V5T 4T5
VANCOUVER, BRITISH COLUMBIA,
Brand Name: VISUDYNE (VERTEPORFIN)
Established Name:
Generic Name: VERTEPORFIN
Dosage Form: FIJ (FOR INJECTION)
Strength: 15 MG PER VIAL

FDA Contacts:			
	L. GORSKI	(HFD-550)	301-827-2090 , Project Manager
	A. FENSELAU	(HFD-550)	301-827-2545 , Review Chemist
	L. NG	(HFD-830)	301-827-2511 , Team Leader

Overall Recommendation:

ACCEPTABLE on 17-MAY-2002 by S. FERGUSON (HFD-324) 301-827-0062

Establishment: 1722344
SP PHARMACEUTICALS LLC
DMF No:
AADA No:

Profile:
OAI Status: NONE
Last Milestone: INSPECTION SCHEDULED
Milestone Date 21-MAY-2002
Responsibilities:

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