CENTER FOR DRUG EVALUATION AND RESEARCH

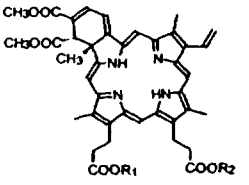
APPLICATION NUMBER:

21-119/S-001

CHEMISTRY REVIEW(S)

Chemistry Review Review #1	1. Division HFD-550	2. NDA Number 21-119
3. Name and Address of Applicant QLT, Inc. 887 Great Northern Way Vancouver, BC Canada V5T 4T5		4. Supplement Number Date SE1 -001 14-AUG-00
5. Name of Drug VISUDYNE™	6. Nonproprietary Name Verteporfin for Injection	
7. Supplement Provides for: Addition of a new indication		8. Amendment(s) 12-APR-01 BC
9. Pharmacological Category Photodynamic therapy for age-related macular degeneration	10. How Dispensed Rx	11. Related Documents
12. Dosage Form Ophthalmic suspension	13. Potency(ies) Verteporfin (15mg/vial)	

14. Chemical Name and Structure see USAN



BPD-MA$_C$: R_1 = CH_3 , R_2 = H
BPD-MA$_D$: R_1 = H , R_2 = CH_3

C $_{41}H_{42}N_4O_8$
M.W. 718.81

9-Methyl and 13-Methyl trans-(±)-18-ethenyl-4,4a-dihydro-3,4-bis(methoxycarbonyl)-4a,8,14,19-tetramethyl-23 *H*,25*H*-benzo[*b*]porphine-9,13-dipropanoate

or

23 *H*,25*H*-Benzo[*b*]porphine-9,13-dipropanoic acid, 18-ethenyl-4,4a-dihydro-3,4-bis(methoxycarbonyl)-4a,8,14,19-tetramethyl-, monomethyl ester, *trans*-

VERTEPORFIN (a 1:1 mixture of BPD-MA $_C$ and BPD-MA$_D$)

15. Comments: In consideration of the request in supplement SE1-001 to add a new indication for Visudyne, this amendment was submitted to request approval for a categorical exclusion from environmental assessment of Visudyne. The supplement does not require any changes in the manufacture of drug substance or drug product.

16. Conclusions and Recommendations

17. Name Signature	Date
Allan Fenselau, Review Chemist	
Concurrence Signature	Date
Linda Ng, Chemistry Team Leader	

cc: NDA 21-119
HFD-550/Division File
HFD-550/CSO/L.Gorski HFD-550/CHEM/A.Fenselau