CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-119/S-001

ADMINISTRATIVE DOCUMENTS

PATENT CERTIFICATION

NDA NUMBER: 21-119

Applicant

QLT PhotoTherapeutics Inc.*
c/o Scott L. Gelbrand, Attorney At Law
Perkins Coie, LLP
1201 Third Avenue, 40th Floor
Seattle, WA 98101-3099
U.S.A.

*a U.S. subsidiary of QLT Inc.
887 Great Northern Way
Vancouver, British Columbia
Canada V5T 4T5

Active Ingredient: verteporfin

Certification: The undersigned certifies, based on her information, advice and belief the following statements.

The above mentioned active ingredient, verteporfin, is the subject of composition claims in U.S. Patent Numbers 4,920,143 and 5,095,030, both of which expire on April 24, 2007. Both patents are owned by The University of British Columbia**, and are exclusively licensed by QLT Inc.

The drug product, Verteporfin for Injection, is the subject of composition claims in:

- U.S. Patent Number 5,214,036, which expires on May 25, 2010, is owned by The University of British Columbia**, and is exclusively licensed by QLT Inc.,
- U.S. Patent Number 5,707,608, which expires on August 02, 2015, and is owned by QLT Inc., and
- U.S. Patent Number 6,074,666, which expires on February 05, 2012, and is owned by QLT Inc.

Methods directed to the use of the drug product in photodynamic therapeutic protocols for the treatment of age-related macular degeneration and related conditions involving unwanted neovasculature in the eye are claimed in:

- U.S. Patent Number 5,770,619, which expires on January 06, 2015 and is owned by The University of British Columbia and exclusively licensed to QLT Inc.,
- U.S. Patent Number 5,798,349 which expires on August 25, 2015 and is co-owned by QLT Inc., the General Hospital Corporation (Boston, MA) and the Massachusetts Eye & Ear Infirmary (Boston, MA),
- U.S. Patent Number 5,756,541 which expires on March 11, 2016, and is owned by QLT Inc., and

- U.S. Patent Numbers 4,883,790 and 5,283,255 both of which expire January 20, 2007 and are owned by The University of British Columbia and exclusively licensed to QLT Inc.

Date: 2 August 2000

Respectfully submitted,

QLT Inc.

Jennifer Kaufman-Shaw

Jennifer Kaufman-Shaw
Director, Intellectual Property

The University of British Columbia**
University-Industry Liaison Office
2194 Health Sciences Mall, Room 331
Vancouver, British Columbia V6T 1Z3
Canada

** U.S. representative: c/o Kate H. Murashige, Attorney At Law
Morrison & Foerster, LLP
12636 High Bluff Drive, Suite 300
San Diego, CA 92130-2071
U.S.A.

The General Hospital Corporation
55 Fruit Street
Boston, MA 02114
U.S.A.

The Massachusetts Eye And Ear Infirmary
243 Charles Street
Boston, MA 02114
U.S.A.

EXCLUSIVITY SUMMARY for NDA # 21-119 SUPPL # 1

Trade Name Visudyne Generic Name Verteporfin for injection

Applicant Name QLT HFD- 550

Approval Date, if known _____

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following question about the submission.

   a) Is it an original NDA?

   YES /___/ NO /✓/

   b) Is it an effectiveness supplement?

   YES /✓/ NO /___/

   If yes, what type? (SE1, SE2, etc.) SE1

   c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

   YES /✓/ NO /___/

   If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

   _____

   _____

   If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

   _____

   _____

d) Did the applicant request exclusivity?

YES /✓/ NO /___/

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

3 years

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. Has a product with the same active ingredient(s), dosage form, strength, route of administration, and dosing schedule, previously been approved by FDA for the same use? (Rx-to-OTC switches should be answered NO-please indicate as such.)

YES /___/ NO /___/

If yes, NDA #_____ Drug Name _____

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

3. Is this drug product or indication a DESI upgrade?

YES /___/ NO /___/

IF THE ANSWER TO QUESTION 3 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# _____ _____

NDA# _____ _____

NDA# _____ _____

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# _____ _____

NDA# _____ _____

NDA# _____ _____

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. IF "YES" GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDA'S AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES /✓/ NO /___/

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES /✓/ NO /___/

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

_____

_____

YES /___/ NO /___/

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /✓/ NO /___/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO /✓/

If yes, explain: _____

_____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO /___/

If yes, explain: _____

_____

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

OCR 3

OCR 4

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES /___/ NO /✓/

Investigation #2 YES /___/ NO /✓/

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

_____ _____

_____ _____

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES /___/ NO /✓/

Investigation #2 YES /___/ NO /✓/

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

_____ _____

_____ _____

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

OCR 3 _____ _____

OCR 4 _____ _____

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1	
IND # [redacted] YES /✓/	NO /___/ Explain: _____
	_____
Investigation #2	
IND # [redacted] YES /✓/	NO /___/ Explain: _____
	_____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1	
YES /___/ Explain _____	NO /___/ Explain _____
_____	_____
_____	_____
Investigation #2	
YES /___/ Explain _____	NO /___/ Explain _____
_____	_____
_____	_____

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES /___/ NO /✓/

If yes, explain: _____

_____

/S/ 8/21/01

Signature Date

Title: Deputy Director

/S/ 8/21/01

Signature of Division Director Date

cc: Original NDA Division File HFD-93 Mary Ann Holovac

FDA Links Searches Check Lists Tracking Link Calendars Reports Help

PEDIATRIC PAGE (Complete for all original application and all efficacy supplements)

View as Word Document

NDA Number:	021119	**Trade Name:**	VISUDYNE (VERTEPORFIN)
Supplement Number:	001	**Generic Name:**	VERTEPORFIN
Supplement Type:	SE1	**Dosage Form:**	
Regulatory Action:	AE	**COMIS Indication:**	TREATMENT OF CNV
Action Date:	2/2/01		

Indication # 1: Visudyne (verteporfin for injection) therapy for the treatment of patients with predominantly classic subfoveal choroidal neovascularization due to macular degeneration, presumed ocular histoplasmosis or pathologic myopia.

Label Adequacy: Does Not Apply

Formulation Needed: NO NEW FORMULATION is needed

Comments (if any): Sponsor has been granted a waiver from conduction pediatirc studies because age related macular degeneration occurs in adult and elderly population.

Ranges for This Indication

Lower Range	Upper Range	Status	Date
Adult	Adult	Waived	

Comments: Sponsor has beengranted a waiver from conduction pediatirc studies because age related macular degeneration occur in adult and elderly population.

Indication # 2: Visudyne (verteporfin for injection) therapy for the treatment of patients with predominantly classic subfoveal choroidal neovascularization due to macular degeneration, presumed ocular histoplasmosis or pathologic myopia.

Label Adequacy: Does Not Apply

Formulation Needed: NO NEW FORMULATION is needed

Comments (if any): Sponsor has been granted a waiver from conduction pediatirc studies because age related macular degeneration occurs in adult and elderly population.

Ranges for This Indication

Lower Range	Upper Range	Status	Date
Adult	Adult	Waived	

Comments: Sponsor has beengranted a waiver from conduction pediatirc studies because age related macular degeneration occur in adult and elderly population.

This page was last edited on 8/21/01

/S/ 8/21/07

Signature Date

/S/ 8/21/01

PEDIATRIC PAGE (Complete for all original application and all efficacy supplements) View Word Document

NDA Number:	021119	**Trade Name:**	VISUDYNE (VERTEPORFIN)
Supplement Number:	001	**Generic Name:**	VERTEPORFIN
Supplement Type:	SE1	**Dosage Form:**	
Regulatory Action:	OP	**COMIS Indication:**	TREATMENT OF CNV
Action Date:	8/14/00		

Indication # 1 The treatment of patients with predominantly classic subfoveal choroidal neovascualrization.

Label Adequacy: Does Not Apply

Forumulation Needed: NO NEW FORMULATION is needed

Comments (if any): Sponsor has been granted a waiver from conduction pediatirc studies because age related macular degeneration occurs in adult and elderly population.

	Lower Range	Upper Range	Status	Date
Adult	Adult	Waived		

Comments: Sponsor has beengranted a waiver from conduction pediatirc studies because age related macular degeneration occur in adult and elderly population.

This page was last edited on 2/1/01

/S/ 2/1/01

Signature Date

QLT Inc. 887 Great Northern Way
Vancouver, BC Canada V5T 4T5
t 604.872.7881
f 604.875.0001
www.qltinc.com

August 14, 2000

Reference: NDA 21-119 S/001 : VISUDYNE™ (verteporfin for injection)

Subject: Certification – Non-use of capacity or services of person debarred under Generic Drug Enforcement Act of 1992.

I, Lawrence D. Mandt, the Vice President, Regulatory Affairs, QLT Inc. (the "Applicant"), hereby certify as follows:

The Applicant did not and will not use in any capacity the services of any person debarred under 21 USC Section 335A (a) and (b), in connection with this NDA.

IN WITNESS WHEREOF, the undersigned has signed this certificate on behalf of QLT Inc. on the 14th day of August 2000.

QLT INC.

By: LMandt

Name: Lawrence D. Mandt

Title: Vice President, Regulatory Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on last page

FOR FDA USE ONLY

APPLICATION NUMBER

NDA 21-119

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
QLT PhotoTherapeutics Inc.	August 14, 2000
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE (FAX) Number** *(Include Area Code)*
604-872-7881	604-707-7373

APPLICANT ADDRESS *(Number, Street, City, State, Country, and ZIP Code or Mail Code, and US License number if previously issued)*:	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, State, and ZIP Code telephone & FAX number)* IF APPLICABLE
c/o Scott L. Gelbrand, Attorney Perkins Coie, LLP 1201 Third Avenue, 40th Floor Seattle, WA 98101-3099	Mr. Jonathan S. Kahan Hogan & Hartson 555 Thirteenth Street, N.W. Washington, DC, USA 20004-1109 tel: (202) 637-5794 fax: (202) 637-5910

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE NUMBER (If previously issued)

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
verteporfin	VISUDYNE™

CHEMICAL/BIOCHEMICAL NAME *(If any)*	CODE NAME *(If any)*
benzoporphyrin derivative monoacids A ring	CL 318,952

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
sterile lyophilized cake	15 mg	intravenous

PROPOSED INDICATIONS FOR USE:

Treatment of patients with predominantly classic subfoveal CNV caused by AMD, or with subfoveal CNV secondary to other macular diseases.

APPLICATION INFORMATION

APPLICATION TYPE (check one) ☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94) ☐ BIOLOGIC APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☒ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION (check one)
☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT
☒ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION
Label extension

PROPOSED MARKETING STATUS (check one) ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 128 — THIS APPLICATION IS ☐ PAPER ☒ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicated whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Application, INDs, NDAs, PMAs 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: ***(Check all that apply)***

X	1.	Index
X	2.	Labeling (check one) ☒ Draft Labeling ☐ Final Printed Labeling
X	3.	Summary (21 CFR 314.50 (c))
	4.	Chemistry section
		A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2)
		B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request)
		C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), CFR 601.2)
X	5.	Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)
	6.	Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)
	7.	Clinical Microbiology (e.g. 21 CFR 314.50 (d) (4))
X	8.	Clinical data section (e.g. 21 CFR 314.50 (d) (5), 21 CFR 601.2)
X	9.	Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)
X	10.	Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)
	11.	Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)
X	12.	Case reports forms (21 CFR 314.50 (f) (2), 21 CFR 601.2)
	13.	Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
X	14.	A patent certification with respect to any patent which claims the drug (21 U.S.C 355 (b) (2) or (j) (2) (A))
	15.	Establishment description (21 CFR Part 600, if applicable)
X	16.	Debarment certification (FD&C Act 306 (k)(1))
	17.	Field copy certification (21 CFR 314.50 (k) (3))
X	18.	User Fee Cover Sheet (Form FDA 3397)
	19.	OTHER (Specify)

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act I agree not to market the product until the drug enforcement administration makes a final scheduling decision.

The data and information in this submission have been reviewed and are certified to be true and accurate.

Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
Jonathan Kahan	Jonathan Kahan, Hogan & Hartson	8/14/00

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
555 Thirteenth Street, N.W., Washington, DC, USA 20004-1109	(202) 637-5794

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Hubert H. Humphrey Building, Room 531-H
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Washington, DC 20201

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FORM FDA 356h (7/97)