

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-119

MICROBIOLOGY REVIEW

Review for Division of Anti-inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550
Office of New Drug Chemistry, Microbiology Staff, HFD-805
Microbiologists's Review No. 2

March 30, 2000

MICROBIOLOGY REVIEWER: Carol K. Vincent

MAR 31 2000

A. 1. NDA No.: 21-119

DRUG PRODUCT NAME: Visudyne™ [verteporfin for injection]

APPLICANT:

DRUG PRODUCT MANUFACTURER:

Quadra Logic Technologies, Inc. (QLT)
520 W. 6th Avenue
Vancouver, British Columbia, Canada

Parkedale Pharmaceuticals, Inc
Rochester, Michigan 48307

2. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
Sterile, lyophilized powder.

3. METHOD(S) OF STERILIZATION:

4. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION:
Photoactive drug injection for photodynamic therapy [PDT] in conjunction with the "Coherent Opal Photoactivator Laser Console and LaserLink Adapter" and "Zeiss 690s Laser with Visulink PDT or Visulink PDT adapter" for the treatment of age-related macular degeneration [AMD].

5. DRUG PRIORITY CLASSIFICATION: 1 P

B. 1. AMENDMENT DATE: January 28, 2000

2. AMENDMENT RECEIVED FOR REVIEW: February 14, 2000

C. REMARKS: This amendment responds to questions from the primary Microbiology review for sterilization process validation information. See MICROBIOLOGIST'S REVIEW NO. 1, DATED DECEMBER 17, 1999.

D. CONCLUSION and RECOMMENDATION:

We recommend approval for QLT Phototherapeutic Inc.'s NDA 21-119, from the microbiology perspective for sterilization process validation information. See "E. REVIEW NOTES:", below.

CC:

Orig. NDA 21-119
HFD-160/Consult/CKVincent [HFD-805]
HFD-550/Chambers/Fenselau/Ng/Gorski
Drafted by: CKVincent/03-23-2000

IS/
Carol K. Vincent
Review Microbiologist [HFD-805]

March 30, 2000

3/31/00

Review for Division of Anti-inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550
Office of New Drug Chemistry, Microbiology Staff, HFD-805
Microbiologists's Review No. 1

December 17, 1999

DEC 17 1999

MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. NDA No.: 21-119

DRUG PRODUCT NAME: Visudyne™ [verteporfin for injection]

APPLICANT:

DRUG PRODUCT MANUFACTURER:

Quadra Logic Technologies, Inc. (QTL)
520 W. 6th Avenue
Vancouver, British Columbia, Canada

Parkedale Pharmaceuticals, Inc
Rochester, Michigan 48307

2. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

Sterile, lyophilized powder.

3. METHOD(S) OF STERILIZATION: [redacted]

4. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION:

Photoactive drug injection for photodynamic therapy [PDT] in conjunction with the "Coherent Opal Photoactivator Laser Console and LaserLink Adapter" and "Zeiss [redacted] 690s Laser with Visulink PDT or Visulink PDT [redacted] adapter" for the treatment of age-related macular degeneration [AMD].

5. DRUG PRIORITY CLASSIFICATION: 1 P

B. 1. DOCUMENT DATE: 08-14-99

2. DOCUMENT RECEIVED FOR REVIEW: 08-24-99

3. COMIS USER FEE DUE DATE: February 12, 2000

4. RELATED DOCUMENTS: [redacted]

C. REMARKS: NDA 21-119, Visudyne [verteporfin for injection], submitted by QTL Phototherapeutics, Inc. is Part I of a multipart application for a combination drug and device product consisting of the photoactive drug, Visudyne [verteporfin for injection], submitted to the Center for Drug Evaluation and Research (CDER), and two device Premarket Approval Applications submitted to The Center for Devices and Radiological Health (CDRH). Clinical studies for this NDA were conducted under [redacted]. The Division of Anti-inflammatory, Analgesic, and Ophthalmic Drug Products (HFD-550) is the reviewing division; CDER is the lead and responsible center for this combination product.

D. CONCLUSION and RECOMMENDATION:

We recommend approval ABLE for QLT Phototherapeutic Inc.'s NDA 21-119, from the microbiology perspective pending satisfactory review of additional sterilization process validation information requested from the applicant. See "E. REVIEW NOTES:" and "Draft of Letter to Applicant", below.

CC:

Orig. NDA 21-119
HFD-160/Consult/CK Vincent [HFD-805]
HFD-550/Chambers/Fenselau/Ng/Gorski
Drafted by: CK Vincent/11-24-99/

IS/
Carol K. Vincent
Review Microbiologist [HFD-805]

12-17-99

12/17/99