



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

RFD 92.04

Food and Drug Administration
Rockville MD 20857

MAR 31 1992

[]
QLT Phototherapeutics Inc.
520 West 6th Avenue
Vancouver, British Columbia
Canada V5Z 4H5

Dear Dr []

This is in response to your inquiry of January 13, 1992 made via FAX concerning the status of the Photofrin System consisting of porfimer sodium and a laser system including optic diffusers that is currently being investigated under IND [] by []

We have reviewed the letter of December 23, 1991 from [] to the Center for Drug Evaluation and Research (CDER) concerning [] understanding of the status of the Photofrin System as a combination product.

Based on the information that we have received in conjunction with the IND, we have concluded that the system meets the definition of a combination product as described in 21 CFR 3.2(e)(3) and is addressed in the CDRH/CDER Intercenter Agreement (Effective Date - October 31, 1991) on pages 9 and 10 (VII.B.1).

We have determined that CDER will be the lead center and the Division of Oncology and Pulmonary Drug Products (DOPDP), the primary reviewing division. All clinical investigations of the drug/device system should continue through the use of the IND process.

DOPDP will consult with CDRH on the device component of the combination product. However, CDER will remain the lead and responsible center for this combination product.

We note that the two components of this combination product will be marketed separately. Therefore, we have determined that two applications are essential to accommodate the products, including the potential for future supplements and separate reporting requirements.

With regard to the premarket applications:

1. Two applications, a new drug application (NDA) and a premarket approval application (PMA), are to be submitted to DOPDP, CDER. Therefore, all time frames associated with review of the applications will be in accordance with the respective regulatory requirements. In addition, all future written communication between the Agency and QLT should be submitted to DOPDP, and will be responded to accordingly.
2. The NDA and PMA applications will be subject to the NDA and PMA regulations, respectively. Therefore, the form and content of each shall be in accordance with either 21 CFR 314.50 (NDA regulations) or 21 CFR 814.20 (PMA regulations).
3. The applications should be submitted together as two companion entities. In order to facilitate document processing, the cover letters to the submissions must clearly and predominantly indicate that they are companion submissions for a combination product. The cover letter should also indicate the DOPDP is the reviewing division. This letter should be included for reference.

The two applications will be assigned an NDA number and a PMA number, respectively. One archival copy of each application, one review copy of the NDA, and three copies of the PMA, jacketed as follows, should be submitted:

Type	Jacket Color
<hr/>	
Archival copy:	
NDA and PMA applications	blue
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Review copy:	
NDA	
Chemistry/ manufacturing controls	red
Nonclinical pharmacology	yellow
Human pharmaco- kinetics/ bioavailability	orange
Clinical	tan
Statistical	green
PMA	
(in accordance with 21 CFR 814.20)	white

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4. An overall Table of Contents should be included in each application. In addition, the summary for both the NDA and the PMA should be inclusive, convening all aspects of both the drug and device.

In addition, please note, we expect that these applications will be subject to an advisory review/committee meeting prior to approval. Members of both the Oncology Drugs Advisory Committee and the Surgical Devices Advisory Panel will be in attendance.

If you have any questions concerning this letter contact Paul Zimmerman, Consumer Safety Officer, Division of Oncology and Pulmonary Drug Products at (301) 443-5197.

Sincerely yours,

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Elizabeth D. Jacobson, Ph.D.
Deputy Director
Center for Devices and
Radiological Health

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D. Bruce Burlington, M.D.
Deputy Director for
Scientific and Medical
Affairs
Center for Drug Evaluation
and Research

cc: [

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