DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-731/S-004

QLT USA, Inc.
2579 Midpoint Drive
Fort Collins, CO 80525-4417

Attention: Caroline Stokl, Ph.D.
Associate Director, Technical Regulatory Affairs

Dear Dr. Stokl:

Please refer to your supplemental new drug application dated May 26, 2006, received May 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ELIGARD® (leuprolide acetate for injectable suspension) 45mg.

We acknowledge receipt of your amendment NDA 21-731/S-004 on May 26, 2006. This supplemental new drug application provides for the use of an 18-gauge, 5/8-inch hypodermic [(b)(4)] needle.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. However, the proposal of [(b)(4)] is not acceptable, [(b)(4)] drug product. [(b)(4)] In your launch of the new packaging, you should request that treating physicians monitor for an increase in incidence and/or severity of injection site adverse events and request that the patients report any injection site adverse events.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels) and/or submitted labeling (package insert and immediate container and carton labels submitted May 26, 2006). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-731/S-004.**" Approval of this submission by FDA is not required before the labeling is used.

Submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text/submitted labeling dated May 26, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kim J. Robertson, Consumer Safety Officer, at (301) 796-1441.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Director
Division of Drug Oncology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling

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

/s/

Robert Justice

9/29/2006 05:39:43 PM