NDA 21-794

QLT USA, Inc.
Attention Cheri Jones, M.S., RAC
Vice President, Regulatory Affairs
2579 Midpoint Drive
Fort Collins, CO 80525

Dear Ms. Jones:

Please refer to your new drug application (NDA) dated August 31, 2004, received September 7, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ACZONE™ (dapsone) Gel, 5%.

We acknowledge receipt of your submissions dated September 10, 15 (2), October 20, November 12, and 15 (2), 2004 and January 3, 19 (2), February 2 (2), 9 (2), 16 (2), 22 (5), 24 (7), 25 (2), March 4 (2), 7, April 7 (3), 8 (3), 19, 20, 21 (2), 22 (2), 27, June 3, 8, 20, 21, 22 (4), 27 (2), 28, and 30 (3, 2-electronic mail), July 1 (2), 5 (2-electronic mail), 6 (electronic mail), and 7 (electronic), 2005.

Your amendment 40 dated June 30, 2005, was not reviewed.

This new drug application provides for the use of ACZONE™ (dapsone) Gel, 5%, for the topical treatment of acne vulgaris. Glucose 6-phosphate dehydrogenase (G6PD) levels should be obtained prior to initiating therapy with ACZONE™ Gel, 5%. In patients with a history of anemia and predisposition to increased hemolytic effect with dapsone (e.g., glucose-6-phosphate dehydrogenase deficiency), closer follow-up for blood hemoglobin levels and reticulocyte counts should be implemented (see PRECAUTIONS). Alternatively, other therapies for acne than ACZONE™ Gel, 5%, may be considered.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We concur with your commitment to revise the 3 gram container label as per your amendment dated June 30, 2005. The final printed 3 gram container label must be identical to the enclosed labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). Marketing the product 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 NDA 21-794.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for pediatric patients below 12 years of age because there are too few children with acne vulgaris.

We remind you of your postmarketing study commitment in your submission dated July 5, 2005. This commitment is listed below.

1. Conduct a randomized, blinded, cross-over safety study with each acne patient treated with ACZONE Gel, 5%, for 12 weeks and vehicle for 12 weeks with at least a two week washout period in at least 50 evaluable G6PD deficient patients with acne vulgaris to further evaluate the risk of hematological adverse events with use of ACZONE Gel, 5%, in this population. Patients with rarer genetic abnormalities such as methemoglobin reductase or the congenital methemoglobinemias may also be studied. Obtain baseline, week 2, and end of each 12 week treatment period laboratory testing including complete blood count, reticulocyte counts, haptoglobin, and LDH levels. Plasma dapsone levels and N-acetyl dapsone levels should be obtained at baseline, week 2, and at the end of each 12 week treatment period. Additionally, plasma dapsone and its metabolite levels should be obtained in relation to adverse events which may be considered dapsone related.

Study Protocol Submission:	November 1, 2005
Study Initiation:	March 1, 2006
Final Study Report Submission:	January 1, 2008

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Final Report", or "Postmarketing Study Commitment Correspondence."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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, please call Frank H. Cross, Jr., M.A., MT (ASCP), CDR, Senior Regulatory Project Management Officer, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Stanka Kukich
7/7/05 03:11:06 PM
sign off for Dr. Jonathan Wilkin