DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-794/S-005

QLT USA, Inc.
2579 Midpoint Drive
Fort Collins, CO 80525
Attention: Elyse Wolff, Vice President, PPM and Operations

Dear Ms. Wolff:

Please refer to your supplemental new drug application dated May 22, 2007, received May 23, 2007, 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 July 23, 2007, September 19, 2007, October 31, 2007, December 12, 2007, and January 9, 2008.

This supplemental new drug application provides for: 1) the removal of the requirement to screen all patients for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to initiating Aczone treatment; and 2) the removal of complete blood count and reticulocyte monitoring during Aczone treatment in patients that are G6PD deficient and in patients with a history of anemia.

This supplement also reports on the following postmarketing study commitment:

Study #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.

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. We also conclude that the above postmarketing study commitment is fulfilled.

CONTENT OF LABELING

As soon as possible, but no later that 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert and text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplement NDA 21-794/S-005".

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submissions of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda/gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

REPORTING REQUIREMENTS

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 Catherine Carr, Regulatory Project Manager, at (301) 796-2011.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Deputy Director
Division of Dermatology and Dental 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

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