DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 77-264

OCT 31 2006

QLT USA, Inc.
Attention: Wendi Young
Regulatory Affairs
2579 Midpoint Drive
Fort Collins, CO 80525-4417

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 1, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Metronidazole Vaginal Gel, 0.75%.

Reference is also made to your amendments dated January 3, January 21, April 13, April 29, and August 11, 2005; and October 10, and October 20, 2006.

We have completed the review of this ANDA and have concluded that adequate information has been submitted to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Metronidazole Vaginal Gel, 0.75%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, MetroGel-Vaginal Gel, 0.75%, of 3M Pharmaceuticals, Inc (3M).

The reference listed drug (RLD) upon which you have based your ANDA, MetroGel-Vaginal Gel, 0.75%, of 3M, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5536743 (the '743 patent) and 5840744 (the '744 patent) are scheduled to expire on July 16, 2013 and January 15, 2008, respectively.

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that both patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Metronidazole

Vaginal Gel, 0.75%, under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against QLT USA, Inc. (QLT) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. This action must have been brought against QLT prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that QLT complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '743 and '744 patents was brought against QLT within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that QLT was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '743 and '744 patents for this drug product. Therefore, with this approval, QLT is eligible for 180-days of generic drug exclusivity for Metronidazole Vaginal Gel, 0.75%. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly 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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

You have agreed to provide the following information after the drug application has been approved. Please provide a comparison of benzene free Carbomer 934P and Carbomer 934P NF, with a level of 0.01% Benzene. To alert the Office of Generic Drugs staff to the fact that you are providing post approval commitment information, please designate on your cover letter that your submission represents a "POST APPROVAL COMMITMENT RESPONSE".

Sincerely yours,

Robert Lewis Lest/for

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research