



ANDA 77-197

Food and Drug Administration
Rockville MD 20857

MAY 24 2006

Altana Inc.
Attention: Robert J. Anderson, Esq.,
Vice President of Scientific Affairs
60 Baylis Road
Melville, NY 11747

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 30, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Metronidazole Topical Lotion, 0.75%.

Reference is also made to your amendments dated July 1, 2004, November 8, 2004, February 28, 2005, and April 19, 2006.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Metronidazole Topical Lotion, 0.75% to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (MetroLotion® Topical Lotion, 0.75% of Galderma Laboratories, L.P.).

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 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.

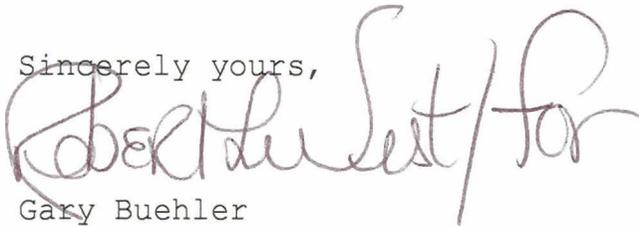
Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in

draft or mock-up form, two copies of both the promotional materials and package insert(s) 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.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Gary Buehler". The signature is written in dark ink and is positioned above the typed name.

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