DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 77-018

JUN 6 2006

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 13, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Metronidazole Topical Gel USP, 0.75%.

Reference is also made to our tentative approval letter dated September 13, 2005, and to your amendments dated April 14, 2005; and April 6, and May 11, 2006.

We have completed the review of this ANDA as amended and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Metronidazole Topical Gel USP, 0.75%, to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, MetroGel Topical Gel, 0.75%, of Galderma Laboratories, LP.

The reference listed drug product (RLD) referenced in your application, MetroGel Topical Gel 0.75% of Galderma Laboratories, LP., was subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book" U.S. Patent No. 4,837,378 (the '378 patent) expired on June 6, 2006.

Your ANDA contains a paragraph III certification to the '378 patent under section 505(j)(2) (A)(vii)(III) of the Act. This certification states that Altana Inc. will not market your Metronidazole Topical Gel USP, 0.75%, prior to the expiration of the patent. The agency recognizes that the patent has expired,

and that the patent no longer blocks the agency from approving your ANDA.

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,

Robert Lumpkin for

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