DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-300

MAY 14 2004

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 17, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fluticasone Propionate Ointment, 0.005%.

Reference is also made to the Tentative Approval letter issued by this office on February 27, 2003, and to your amendments dated March 15, April 15, April 16, and May 12, 2004.

We have completed the review of this tentatively approved 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 Fluticasone Propionate Ointment, 0.005%, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Cutivate® Ointment, 0.005%, of GlaxoSmithKline).

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

Post-marketing reporting requirements for this abbreviated 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(s) directly to:

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

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

You have been requested to provide information after the drug application has been approved. Specifically, you will perform a comparative study measuring the viscosity of your product (b)(4) (b)(4). You have committed to provide the viscosity study and data within 60 days of final approval. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response". To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE".

Sincerely yours,

(b)(6)

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