



ANDA 77-287

Food and Drug Administration  
Rockville MD 20857

SEP 19 2006

ALTANA Inc  
Attention: Robert J. Anderson  
P.O.Box 2006  
Melville, NY 11747

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 23, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Prednicarbate Cream, 0.1% (Emollient).

Reference is also made to your amendments dated January 27, and April 4, 2006.

We have completed the review of this ANDA 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 Prednicarbate Cream, 0.1% (Emollient) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Dermatop of Sanofi Aventis US).

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler". The signature is written in a cursive style with a large, prominent initial "G".

Gary Buehler

Director

Office of Generic Drugs

Center for Drug Evaluation and Research