



ANDA 76-654

Food and Drug Administration  
Rockville MD 20857

AUG 3 2005

Taro Pharmaceuticals U.S.A., Inc  
Attention: Kalpana Rao  
U.S. Agent for: Taro Pharmaceutical Industries Ltd.  
5 Skyline Drive  
Hawthorne, NY 10532

Dear Madam:

This is in reference to your abbreviated new drug application dated January 31, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Hydrocortisone Butyrate Cream USP, 0.1%.

Reference is also made to your amendments dated February 9, March 19 (two amendments), October 14, December 1, 2004 and March 2, 2005.

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 Hydrocortisone Butyrate Cream USP, 0.1% to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Locoid<sup>®</sup> Cream, 0.1% of Ferndale Laboratories, Inc).

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.

Postmarketing 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.

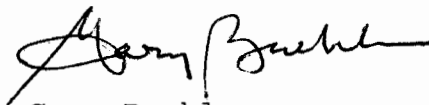
Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit,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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary Buehler", written in a cursive style.

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