DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-477

Taro Pharmaceuticals U.S.A., Inc.
Attention: Srinivasa Rao
Director, Regulatory Affairs
3 Skyline Drive
Hawthorne, NY 10532

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 24, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Betamethasone Dipropionate Lotion USP, 0.05% (Augmented).

Reference is also made to the tentative approval letter issued by this office on January 25, 2006, and to your amendments dated May 17, 2006, and February 22, and May 7, 2007.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Betamethasone Dipropionate Lotion USP, 0.05% (Augmented) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Diprolene Lotion, 0.05% (Augmented), of Schering Corporation (Schering).

The reference listed drug product (RLD) referenced in your application, Schering Corp.'s Diprolene Lotion, 0.05% (Augmented) 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. 4,775,529 (the '529 patent) expired on May 21, 2007.

Your ANDA contains a Paragraph III Certification to the '529 patent under section 505(j)(2) (A)(vii)(III) of the Act. This certification states that Taro Pharmaceuticals U.S.A., Inc. will not market Betamethasone Dipropionate Lotion USP, 0.05% (Augmented) prior to the expiration of the '529 patent. The agency recognizes the '529 patent has expired, and that this patent no longer blocks the agency from approving your application.

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 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,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
5/21/2007 03:32:10 PM
for Gary Buehler