CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75279

APPROVAL LETTER

ANDA 75-279

MAY 28 1999

Taro Pharmaceuticals USA, Inc.
Attention: Lorraine Sachs
U.S. Agent for: Taro Pharmaceuticals, Inc.
5 Skyline Drive
Hawthorne, NY 10532

Dear Madam:

This is in reference to your abbreviated new drug application dated December 19, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Clobetasol Propionate Gel, 0.05%.

Reference is also made to your amendments dated February 3, March 31, and August 21, 1998; and February 15, February 25, March 29, May 5, May 11, and May 26 (2 submissions), 1999.

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 that your Clobetasol Propionate Gel, 0.05%, is bioequivalent and, therefore, therapeutically equivalent, to the listed drug (Temovate® Gel 0.05%, of Glaxo Wellcome, Inc.).

Under 21 CFR 314.70, 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. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FDA-2253 at the time of their initial use.

Sincerely yours,

/S/

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

5/28/99