DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-679

DEC 21 2004

Taro Pharmaceuticals U.S.A., Inc.
Attention: Kalpana Rao
5 Skyline Drive
Hawthorne, NY 10532

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 28, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Mometasone Furoate Cream USP, 0.1%.

Reference is also made to the Tentative Approval letter issued by this office on December 3, 2004, and to your amendment dated December 21, 2004.

The listed drug product (RLD) referenced in your application, Elocon Cream, 0.1%, of Schering Corporation, is subject to a period of patent protection. The following patent for this drug product is currently listed in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book):

Patent Number	Expiration Date
4,808,610 (the '610 patent)	April 2, 2007

Your application contains a patent certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '610 patent will not be infringed by your manufacture, use, or sale of Mometasone Furoate Cream USP, 0.1% under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Taro Pharmaceuticals U.S.A., Inc. (Taro) for infringement of the '610 patent which was the subject of the paragraph IV certification. This action must have been brought against Taro prior to the expiration of 45 days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that

Taro complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '610 patent was brought against Taro within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).[1]

At the time of our tentative approval letter, we were unable to grant full approval to your ANDA because of the eligibility of Agis Industries (1983) Ltd. (Agis) for 180-day generic drug exclusivity for this drug product under section 505(j)(5)(B)(iv) of the Act. As you are aware, effective December 20, 2004, Agis has relinquished its eligibility for 180-day exclusivity, thereby permitting the immediate full approval of your application. Furthermore, by relinquishing it eligibility for 180-day exclusivity, Agis recognizes that the relinquishment will also apply to all ANDAs for this drug product, and that the Office of Generic Drugs may approve any such application that is otherwise ready for approval without regard to the 180-day exclusivity period specified in Section 505(j)(5)(B)(iv).

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 Mometasone Furoate Cream, 0.1%, to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Elocon Cream 0.1%, of Schering Corporation.

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

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[1] Because information on the '610 patent was submitted to FDA before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescriptionb Drug, Improvement and Modernization Act (MMA)(Public Law 108-173) was enacted. See MMA § 1101(c)(3).

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 materials for any subsequent advertising or promotional campaign 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,

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