DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 201615

Tolmar Inc.
Attention: Michelle R. Ryder
Senior Director, Regulatory Affairs
701 Centre Ave.
Fort Collins, CO 80526

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 29, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Calcipotriene 0.005% and Betamethasone Dipropionate 0.064% Ointment.

Reference is also made to the tentative approval letter issued by this office on February 29, 2012, and to your amendments dated October 15, and December 17, 2012.

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 Calcipotriene 0.005% and Betamethasone Dipropionate 0.064% Ointment, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Taclonex Ointment, 0.005%/0.064% of Leo Pharmaceutical Products, Ltd. (LEO).

The RLD upon which you have based your ANDA, Leo's Taclonex Ointment, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,763,426 (the '426 patent)	June 9, 2015
6,753,013 (the '013 patent)	January 27, 2020
RE39706 (the '706 patent)	June 9, 2015

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Calcipotriene 0.005% and Betamethasone Dipropionate 0.064% Ointment, under this ANDA. You have notified the agency Tolmar Inc. (Tolmar) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '706 patent was brought against Tolmar within the statutory 45-day period in the United States District Court for the District of Delaware [LEO Pharma A/S v. Tolmar Inc., Civil Action No. 1:10-cv-00715-UNA]. Although this litigation remains ongoing, the 30 months period identified in section 505(j) (5) (B) (iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that Tolmar was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the listed patents. Therefore, with this approval, Tolmar is eligible for 180 days of generic drug exclusivity for Calcipotriene 0.005% and Betamethasone Dipropionate 0.064% Ointment. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
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

01/14/2013

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.