DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078548

Nycomed U.S., Inc.
Attention: Robert J. Anderson, Esq.
Vice President, Scientific Affairs
60 Baylis Road
P.O. Box 2006
Melville, NY 11747

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 16, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Imiquimod Cream, 5%.

Reference is also made to your amendments dated April 27 and October 2, 2007; January 22, February 13, March 31, June 12, July 25, August 15, August 22 and August 28, 2008; March 13, 2009; and January 20, 2010.

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 Imiquimod Cream, 5%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Aldara Cream, 5%, of Graceway Pharmaceuticals, LLC. (Graceway).

The RLD upon which you have based your ANDA, Graceway's Aldara Cream, 5%, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 4,689,338 (the '338 patent) and 5,238,944 (the '944 patent) are scheduled to expire (with pediatric exclusivity added) on February 25, 2010, and February 24, 2011, respectively.

With respect to the ‘944 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Imiquimod Cream, 5%, under this ANDA. You have notified the agency that Nycomed U.S., Inc. (Nycomed) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the ‘944 patent was brought against Nycomed within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

We note that the ‘338 patent has expired.

With respect to 180-day generic drug exclusivity, we note that Nycomed was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '944 patent. Therefore, with this approval, Nycomed is eligible for 180 days of generic drug exclusivity for Imiquimod Cream, 5%. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins. The agency notes that Nycomed failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. However, the agency has determined that the failure to obtain tentative approval within 30 months was caused by the agency’s ongoing review of the requirements for approval of Imiquimod Cream, 5%, and therefore Nycomed did not forfeit eligibility for 180-day generic drug exclusivity. See section 505(j)(5)(D)(i)(IV) of the Act.

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] 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. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence - SPL for Approved ANDA 078548".***

Sincerely yours,

{See appended electronic signature page}

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-78548	ORIG-1	NYCOMED US INC	IMIQUIMOD

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
02/25/2010
Deputy Director, for Gary Buehler