DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-305

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 17, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Calcipotriene Topical Solution, 0.005% (Scalp Solution).

Reference is also made to your amendments dated December 15, 2006, November 8, 2007 (two amendments), and November 19, 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 Calcipotriene Topical Solution, 0.005% (Scalp Solution) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Dovonex Scalp Solution, 0.005% of Leo Pharma.

The RLD upon which you have based your ANDA, Dovonex Scalp Solution 0.005% of Leo Pharma, 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. 5,763,426 (the '426 patent) and RE39706 (the '706 patent) are both scheduled to expire on June 9, 2015.

With respect to the '426 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '426 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Calcipotriene Topical Solution, 0.005% (Scalp Solution), 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 is brought against Nycomed US, Inc. (Nycomed) for infringement of the patent that was the subject of the paragraph IV certification. You have notified the agency that Nycomed US, Inc. complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement 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).

The '706 patent was listed after submission of your ANDA. The amendment containing your paragraph IV certification with respect to the '706 patent was submitted on April 28, 2008, and you provided notice of this certification to Leo Pharma at the same time. For these reasons, there

is no statutory basis for the ‘706 patent to be a bar to immediate approval of your ANDA. See section 505(j)(5)(B)(iii) of the Act.

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 '426 patent. Therefore, with this approval, Nycomed is eligible for 180 days of generic drug exclusivity for Calcipotriene Topical Solution, 0.005% (Scalp Solution). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of 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.

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(s) 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.

FDA’s field staff has not completed the validation of the regulatory methods submitted in your application. It is the policy of the Office of Generic Drugs to proceed with approval of your application while this process continues. We acknowledge receipt of your commitment to cooperate with the agency to resolve any methods validation related deficiencies which may be identified.

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/

Gary Buehler

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