DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018707/S-012
NDA 018702/S-011

SUPPLEMENT APPROVAL

Nycomed US Inc.
Attention: Ralph N. Landau, Ph.D.
Sr. VP, Research & Development
60 Baylis Road
Melville, NY 11747

Dear Dr. Landau:

Please refer to your Supplemental New Drug Application, NDA 018707/S-012, dated November 15, 2010, received November 16, 2010, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aclovate (alclometasone dipropionate) Cream, 0.05%.

We acknowledge receipt of your amendments dated February 28, 2011 and March 3, 2011.

Please also refer to your Supplemental New Drug Application, NDA 018702/S-011, dated March 3, 2011, received March 4, 2011, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aclovate (alclometasone dipropionate) Ointment, 0.05%.

These "Prior Approval" supplemental new drug applications provide for incorporation of the findings of the Tg.AC mouse assay conducted with Aclovate Cream under the PRECAUTIONS, General and PRECAUTIONS, Carcinogenesis, Mutagenesis, and Impairment of Fertility sections of the labeling.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Please note that if you intend to re-market the 45 g packaging configuration, you should notify the Agency in advance because a supplement may be needed to support its re-marketing.

If you have any questions, call Kim Shiley, Regulatory Project Manager, at (301) 796-2117.

Sincerely,

{See appended electronic signature page}

Tatiana Oussova, M.D., M.P.H.
Deputy Director for Safety
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

TATIANA OUSSOVA
04/05/2011