DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021152/S-005

FULFILLMENT OF POSTMARKETING COMMITMENT SUPPLEMENT APPROVAL

Nycomed U.S. Inc.
Attention: Robert J. Anderson, Esq.
General Counsel & V.P., Regulatory Affairs
60 Baylis Road
Melville, NY 11747

Dear Mr. Anderson:

We refer to your supplemental New Drug Application (sNDA) dated May 27, 2010, received May 27, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cutivate® (fluticasone propionate) Lotion, 0.05%.

We also acknowledge receipt of your amendments dated September 17 and October 8, 2010, and February 10, 2011.

Your submission contained the final report for the following postmarketing commitment listed in the March 31, 2005 approval letter.

371-2. Conduct a study to determine the photoco-carcinogenic potential of CUTIVATE® (fluticasone propionate) Lotion, 0.05%.

Dose Range Finding Study: by October 1, 2005
Protocol Submission: by August 1, 2006
Study Start: by February 1, 2007
Final Report Submission: by August 1, 2009

We have reviewed your final study report and conclude that the above commitment was fulfilled.

Your submission also contained proposed labeling changes associated with the above mentioned final study report.

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

We remind you that there is a postmarketing commitment listed in the March 31, 2005 approval letter that is still open.

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).

If you have any questions, call Paul Phillips, Regulatory Project Manager, at (301) 796-3935.

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:
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
05/12/2011