DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019958/S-017

SUPPLEMENT APPROVAL

Nycomed US Inc.
Attention: Robert J. Anderson, Esq.
General Council & V.P., Regulatory Affairs
60 Baylis Rd.
P.O. Box 2006
Melville, NY 11747

Dear Mr. Anderson:

Please refer to your Supplemental New Drug Application (sNDA) dated April 25, 2008, received April 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cutivate® (fluticasone propionate) Cream, 0.05%.

We acknowledge receipt of your amendments dated November 20, 2008: March 20, 2009: March 9, June 21, August 11, and August 20, 2010.

The November 20, 2008, submission constituted a complete response to our October 24, 2008, action letter. The March 9, 2010, submission constituted a complete response to our May 1, 2009 action letter.

This "Prior Approval" supplemental new drug application provides for changes in the package insert to include information about the presence of formaldehyde in the product.

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.

Also provide your plans on how you intend to inform physicians regarding these labeling changes.

CONTENT OF LABELING

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 to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 pending "Changes Being Effected" (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.

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 CDERMedWatchSafetyAlerts@fda.hhs.gov, and 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}

Stanka Kukich, M.D.
Deputy Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19958	SUPPL-17	ALTANA INC	CUTIVATE

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

/s/

STANKA KUKICH
09/03/2010