DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022483/S-002

APPROVAL LETTER

Graceway Pharmaceuticals, LLC
Attention: Tom W. Der
Director, Regulatory Affairs
340 Martin Luther King Jr. Blvd.
Suite 500
Bristol, TN 37620

Dear Mr. Der:

Please refer to your Supplemental New Drug Application (sNDA) dated June 22, 2010, received June 23, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyclara (imiquimod) Cream, 3.75%.

We acknowledge receipt of your amendments dated September 9, October 29, and November 2, 2010, March 31, July 29, August 17 and 23, September 9, 16 and 16, 2011. The March 31, 2011 submission constituted a complete response to our January 24, 2011 action letter.

This supplemental new drug application proposes the use of a pump container closure system.

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 and with the minor editorial revisions listed below.

1. In the Full Prescribing Information, Section 2, Dosage and Administration, subsection 2.1, Actinic Keratosis, a new paragraph was created. The first sentence of the final paragraph was revised from "Patients should be prescribed no more than 2 boxes…" to "Prescribe no more than 2 boxes…"

2. In the Full Prescribing Information, Section 6, Adverse Reactions, subsection 6.3, Postmarketing Experience, periods were removed from the listing of adverse reactions.

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, except with the revisions listed, the enclosed labeling (text for the package insert, text for the patient 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 via 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 with the revisions listed 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed.

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 Cristina Attinello, Regulatory Project Manager, at (301) 796-3986.

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

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

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
09/29/2011