DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-723/S-020

Graceway Pharmaceuticals, LLC
Attention: John A. Bellamy
Executive Vice President and General Counsel
340 Edgemont Avenue, Suite 500
Bristol, TN 37620

Dear Mr. Bellamy:

Please refer to your new drug application (NDA) dated September 21, 2006, received September 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aldara™ (imiquimod) Cream, 5% .

We acknowledge receipt of your submissions dated October 12, November 8, 16, 29 (2), December 5, 7, and December 21, 2006, January 12, 23, and 31, February 13, 15, and March 22, 2007(facsimile).

This new drug application provides for the addition of pediatric safety data in the **INDICATIONS and USAGE** and **USE IN SPECIFIC POPULATIONS: Pediatric Use** sections of the labeling.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 20-723/S-020**." Approval of this submission by FDA is not required before the labeling is used.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

We remind you of your postmarketing study commitments dated March 2, 2004. These commitments are listed below.

2. Conduct a study of the safety and efficacy of topical imiquimod in the treatment of actinic keratoses at other locations than the face or scalp, e.g. the extremities.

   Protocol Submission: by September, 2004
   Study Start: by June, 2005
   Final Report Submission: by August, 2007

3. Conduct a study of the short-term (up to 16 weeks) and longer term (for at least 1 year with 2 or more separate treatment applications to the same treatment area) safety of treating contiguous and non-contiguous surface areas larger than 25 cm^2 with numbers of patients as per ICH E1A. The maximum amount of drug and surface area studied should be guided by limitations posed by available systemic bioavailability and safety information. The areas treated in such a study should include face and scalp, but should also include other locations (e.g. extremities as per commitment #2 above). Pharmacokinetic data to be obtained from a subset of at least 12 evaluable patients with maximal exposure from clinical studies above.

   Protocol Submission: by September, 2004
   Study Start: by June, 2005
   Final Report Submission: by December, 2007

We also remind you of your postmarketing study commitment dated July 13, 2004. This commitment is listed below.

1. The sponsor should continue to submit the follow-up data (with analysis) from study 1412-IMIQ through completion of the study in the form of interim reports on September 30 each year (beginning in 2005) with submission of the final study report by September 30, 2007.

   Protocol Submission: already submitted
   Study Start: ongoing
   Final Report Submission: September 30, 2007

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

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 Margo Owens, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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
3/22/2007 06:31:06 PM
Sign off for Susan Walker, Division Director