DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-723/S-015

3M Pharmaceuticals
Attention: Mark A. Morken, R.Ph.
Senior Regulatory Associate
3M Center, Building 270-3A-08
St. Paul, MN 55144-1000

Dear Mr. Morken:

Please refer to your supplemental new drug application dated May 1, 2003, received May 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aldara (imiquimod) Cream, 5%.

We acknowledge receipt of your submission dated August 27, September 12, November 10 and 13, December 10 and 22, 2003 and January 6 (2), 12, 15, 22, and 23, 2004.

This supplemental new drug application provides for the use of Aldara (imiquimod) Cream, 5% for the topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adults.

We completed our review of this application, as amended. This application 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 text for the patient package insert).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-723/S-015." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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

1. Conduct a phototoxicity study which includes the light absorption spectra from 280 to 320 nm.

Protocol Submission:	by September, 2004
Study Start:	by March, 2005
Final Report Submission:	by March, 2006

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

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**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Ginny Giroux, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
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/

Jonathan Wilkin
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