DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-723/S-011
NDA 20-723/S-012

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

Dear Mr. Morken:

Please refer to your new supplemental drug applications dated July 23, 2001, received July 24, 2001 (S-011) and June 28, 2002, received July 3, 2002 (S-012), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aldara (imiquimod) Cream, 5%.

These supplemental new drug applications provide for the inclusion of the following into the labeling: 1) in the INDICATIONS AND USAGE section, labeling allowing use down to age 12 years, and in the Pediatric Use section wording establishing safety and efficacy down to 12 years (S-011) and 2) in the Information for Patients section, additional information instructing female patients to avoid using the product in the vagina (S-012). It is also noted that the changes in the storage statement, in the How Supplied Section, was approved, February 18, 1998, in S-004.

We have completed the review of these applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please 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 ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 20-723/S-011 and S-012." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and 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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