



NDA 20-723/S-018

3M Pharmaceuticals
Attention: Ann Hubberts
Senior, Regulatory Associate
3M Center, Building 270-3A-08
St. Paul, MN 55144-1000

Dear Mrs. Hubberts:

Please refer to your supplemental new drug application dated February 14, 2005, received February 16, 2005, 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 April 18, July 26 (facsimile), 29(facsimile), August 4 (facsimile), and 8 (facsimile), 2005.

This supplemental new drug application provides for revisions to the label under the PRECAUTIONS: General Subsection, Pregnancy: Category C section, the addition of a POSTMARKETING ADVERSE EVENTS section and revisions to Patient Information Insert (Patient Package Insert).

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 enclosed labeling (text for the package insert, text for the patient package insert).

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 supplement NDA 20-723/S-018.**" Approval of this submission by FDA is not required before the labeling is used.

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

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 Felecia Curtis, 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 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
8/9/05 12:21:39 PM
sign off for Dr. Jonathan Wilkin, Division Director