CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-723/S016

Trade Name: Aldara 5% Cream

Generic Name: imiquimod

Sponsor: 3M Pharmaceuticals

Approval Date: July 14, 2004

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APPLICATION NUMBER:

NDA 20-723/S-016

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APPLICATION NUMBER:

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APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 20-723/S-016

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 June 9, 2003, received June 10, 2003, 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 September 16 and October 23, 2003; and February 4, 13, 19, and 24, and March 1, 2004.

This supplemental new drug application provides for the use of Aldara (imiquimod) Cream, 5% for the treatment of superficial basal cell carcinoma.

We completed our review of this application, and it is approvable for immunocompetent adults for the topical treatment of biopsy-confirmed, primary superficial basal cell carcinoma (sBCC), with a maximum tumor diameter of 2.0 cm, and location on the trunk (excluding anogenital skin) or extremities, when conventional methods are impractical and as part of a treatment regimen that includes post-treatment follow-up visits with a physician knowledgeable in diseases of the skin.

Before the application may be approved, however, you must address the following deficiencies:

1. Submit two-year data, with analysis, from the ongoing long-term study, 1412-IMIQ for review by the Agency.

2. For the CARTON labels the following revisions are recommended:
   Insert the statement "Not for Ophthalmic Use" on the front panel.
   Replace statement [redacted] with "For Dermatologic Use Only".

3. For the CONTAINER labels, the following information should be included:
   "Store below 25 ° C (77 ° F). Avoid freezing".
   "Not for Ophthalmic Use"
   "For Dermatologic Use Only"

Should you determine that the space is too small to include the three items listed above for the container label, please submit a draft label showing that these revisions are not possible even by reducing the font size. We would be willing to address this issue after reviewing your draft label for the container.

4. Submission of revised draft labeling with the requested information as provided with the enclosure.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all non-clinical and clinical studies of the drug under consideration regardless of indication, dosage form, or dose level.

1. Describe in detail any significant changes or findings in the safety profile.

2. When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:

   - Present new safety data from the studies for the proposed indication using the same format as the original NDA submission.
   - Present tabulations of the new safety data combined with the original NDA data.
   - Include tables that compare frequencies of adverse events in the original NDA with the retabulated frequencies described in the bullet above.
   - For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.

3. Present a retabulation of the reasons for premature study discontinuation by incorporating the drop-outs from the newly completed studies. Describe any new trends or patterns identified.

4. Provide case report forms and narrative summaries for each patient who died during a clinical study or who did not complete a study because of an adverse event. In addition, provide narrative summaries for serious adverse events.

5. Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original NDA data.

6. Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.

7. Provide English translations of current approved foreign labeling not previously submitted.

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:

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
4/7/04 12:05:57 PM