

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-844

APPROVAL LETTER



NDA 21-844

Barry Calvarese, M.S.
Vice President, Regulatory and Clinical Affairs
Dow Pharmaceutical Sciences
1330 Redwood Way
Petaluma, CA 949-1169

Dear Mr. Calvarese:

Please refer to your new drug application\ (NDA) dated December 19, 2005, received December 21, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for **Desonate™ (desonide) Gel 0.05%**.

We acknowledge receipt of your submissions dated January 30, March 20, April 19, August 16, August 18, August 28, August 30, September 14, October 2, and October 10, 16, 17 (electronic mail), 2006.

This new drug application provides for the use of **Desonate™ (desonide) Gel 0.05% for the treatment** of mild to moderate atopic dermatitis.

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 and the immediate container and carton labels submitted October 17, 2006. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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>, 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.

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 note that you have fulfilled the pediatric study requirement for this application.

We remind you of your postmarketing study commitment(s) in your submission dated September 14, 2006. These commitments are listed below.

1. The applicant commits to conducting a dermal carcinogenicity study in Tg.AC mice with Desonate (desonide) Gel 0.05%.

4-week dose range finding study report (plus TPA feasibility study)	by May 1, 2007
Study protocol submission	by November 1, 2007
Study start date	by August 1, 2008
Final report submission	by May 1, 2010

2. The applicant commits to conducting a study to determine the photoco-carcinogenic potential of Desonate (desonide) Gel 0.05%, (13 week Photosafety study in mice).

3-week pilot study report (plus single dose SKH1-hr mice studies for PK, irritancy and UVR response)	by May 1, 2007
Study protocol submission	by August 1, 2007
Study start date	by February 1, 2008
Final report Submission	by February 1, 2009

Submit 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. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **“Postmarketing Study Commitment Protocol”, “Postmarketing Study Commitment Final Report”, or “Postmarketing Study Commitment Correspondence.”**

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

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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If you have any questions, call Shalini Jain, Regulatory Project Manager at (301) 796-0692.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
Division Director
Division of Dermatology & 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

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sign off for Dr. Susan Walker, Division Director