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APPLICATION NUMBER:

21-835

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-835

Dow Pharmaceutical Sciences
Attention: Barry M. Calvarese, MS
Vice President, Regulatory and Clinical Affairs
1330 Redwood Way
Petaluma, CA 94954-1169

Dear Mr. Calvarese:

Please refer to your new drug application (NDA) dated December 22, 2004, received December 27, 2004, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for CLOBEX (clobetasol propionate) Spray, 0.05%.

We acknowledge receipt of your submissions dated March 8, April 22, July 8, August 15, August 29, September 26, and October 4, 2005. Electronic mail dated October 19 and 26, 2005.

This new drug application provides for the use of CLOBEX (clobetasol propionate) Spray, 0.05% for the treatment of moderate to severe psoriasis.

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 (text for the package insert). The final printed proprietary name on the carton and container must be identical to the name on the enclosed labeling.

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 NDA 21-835.**" 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 as stated in your letter dated October 26, 2005. These commitments with a recommended timeline are listed below.

1. The applicant commits to conduct a dermal carcinogenicity study with clobetasol propionate and appropriate vehicles.

90-day dose range-finding study report:	December 16, 2005
Study protocol submission:	March 16, 2006
Study start date:	November 16, 2006
Final report submission:	November 16, 2009

2. The applicant commits to conducting a study to determine the photoco-carcinogenic potential of clobetasol propionate and appropriate vehicles.

90-day dose range-finding study report:	December 16, 2005
Study protocol submission:	March 16, 2006
Study start date:	November 16, 2006
Final report submission:	November 16, 2009

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 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 product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, the Division of Dermatologic & Dental Drug Products, 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

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, please call Kalyani Bhatt, 301-796-2110.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, MD
Acting Division Director,
Division of Dermatology & Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research